

2,500,000 Shares



Ordinary Shares

This is Strongbridge Biopharma plc’s initial U.S. public offering. We are selling 2,500,000 of our ordinary shares. The initial public offering price is \$10.00 per ordinary share.

Our ordinary shares are currently quoted on the Norwegian Over-The-Counter System, or NOTC A-list under the symbol “SBBP.” On October 14, 2015, the last reported sale price of our ordinary shares on the NOTC was NOK 120 per share, equivalent to a price of \$14.82 per share, assuming an exchange rate of NOK 8.0982 per U.S. dollar. No other public market currently exists for our ordinary shares.

Our ordinary shares have been approved for listing on The NASDAQ Global Select Market under the symbol “SBBP.”

We are an “emerging growth company,” as defined by the Jumpstart Our Business Startups Act of 2012, and as such, have elected to comply with certain reduced public company reporting requirements for this prospectus and future filings.

Investing in our ordinary shares involves risks. See the section titled “Risk Factors” beginning on page 13 of this prospectus.

	Per Share	Total
Public offering price	\$10.00	\$25,000,000
Underwriting discount ⁽¹⁾	\$ 0.70	\$ 1,750,000
Proceeds, before expenses, to us	\$ 9.30	\$23,250,000

(1) We have agreed to reimburse the underwriters for certain expenses. See “Underwriting.”

Certain of our existing shareholders who beneficially own more than 5% of our ordinary shares and their affiliates have indicated an interest in purchasing up to an aggregate of \$20.0 million of our ordinary shares in this offering at the initial public offering price per share. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters may determine to sell more, less or no shares in this offering to any of these entities, or any of these entities may determine to purchase more, less or no shares in this offering. The underwriters will receive the same underwriting discount on any ordinary shares purchased by these entities as they will on any other shares sold to the public in this offering.

The underwriters may also exercise their option to purchase up to an additional 375,000 ordinary shares from us, at the public offering price, less the underwriting discount, for 30 days after the date of this prospectus.

Neither the Securities and Exchange Commission, any U.S. state securities commission, the Central Bank of Ireland nor any other foreign securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The underwriters expect to deliver the shares to purchasers in the offering on or about October 21, 2015.

Stifel

JMP Securities

Roth Capital Partners

Arctic Securities

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Neither we nor the underwriters have authorized anyone to provide you with information that is different from that contained in this prospectus, any amendment or supplement to this prospectus, or in any free writing prospectus we may authorize to be delivered or made available to you. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. We and the underwriters are offering to sell ordinary shares and seeking offers to subscribe for ordinary shares only in jurisdictions where offers and sales are permitted. The information contained in this prospectus is accurate only as of the date on the front of this prospectus, regardless of the time of delivery of this prospectus or any sale of ordinary shares.

For investors outside of the United States: Neither we nor any of the underwriters have taken any action to permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. You are required to inform yourselves about and to observe any restrictions relating to this offering and the distribution of this prospectus.

PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus and does not contain all of the information that you should consider in making your investment decision. Before deciding to invest in the ordinary shares, you should read this entire prospectus carefully, including the sections titled “Risk Factors,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Business” and our consolidated financial statements, including the notes thereto, included elsewhere in this prospectus. Unless otherwise indicated or the context otherwise requires, all references in this prospectus to “Strongbridge” or the “Company,” “we,” “our,” “ours,” “us” or similar terms refer to Strongbridge Biopharma plc, together with its consolidated subsidiaries (including Cortendo AB, its predecessor, and current subsidiaries), and “dollar,” “US\$” or “\$” refer to U.S. dollars. Unless otherwise indicated in this prospectus, all share amounts and per share amounts included in this prospectus have been retroactively adjusted, where applicable, to reflect (i) the exchange offer described below, which settled on September 8, 2015, pursuant to which holders of 99.582% of the outstanding shares of Cortendo AB tendered their shares in exchange for beneficial interests in ordinary shares of Strongbridge Biopharma plc in the form of depositary receipts (or, in the case of non-accredited holders of Cortendo AB shares located within the United States, in exchange for cash), and (ii) immediately following the settlement of its exchange offer, a reverse stock split of the outstanding ordinary shares of Strongbridge Biopharma plc (including the beneficial interests in such shares in the form of depositary receipts) at a ratio of 1-for-11.

Overview

We are a biopharmaceutical company focused on the development, in-licensing, acquisition and eventual commercialization of multiple complementary products and product candidates within franchises that target rare diseases. Our primary focus has been to build our rare endocrine franchise, which includes product candidates for the treatment of endogenous Cushing’s syndrome and acromegaly, two rare diseases with a high unmet need for innovative treatment options. Given the well-identified and concentrated prescriber base addressing our target markets, we believe we can use a small, focused sales force to effectively market our products, if approved, in the United States, the European Union and other key global markets. We believe that our ability to execute on this strategy is enhanced by the significant clinical development and commercial experience of key members of our management team. We also intend to identify and in-license or acquire products or product candidates that would be complementary to our existing rare endocrine franchise or that would form the basis for new rare disease franchises. We believe this approach will enable us to maximize our commercial potential by further leveraging our existing resources and expertise.

Our rare endocrine franchise includes the following product candidates:

- *COR-003 (levoketoconazole), a cortisol synthesis inhibitor, in Phase 3 clinical development for the treatment of endogenous Cushing’s syndrome.* Endogenous Cushing’s syndrome is a rare endocrine disorder characterized by sustained elevated cortisol levels that most commonly result from a benign tumor of the pituitary gland. We believe that COR-003 has the potential to become the new standard of care for the drug therapy of endogenous Cushing’s syndrome. COR-003 may provide a favorable efficacy, safety and tolerability profile compared to current drug therapies, including ketoconazole, the most commonly used drug therapy for endogenous Cushing’s syndrome. COR-003 has been granted orphan drug designation by the U.S. Food and Drug Administration, or the FDA, and the European Medicines Agency, or the EMA. We are developing COR-003, a single enantiomer of ketoconazole, as a new chemical entity, or NCE, under the FDA 505(b)(2) regulatory approval pathway, and intend to reference the FDA’s prior conclusions of safety and effectiveness for ketoconazole. Molecules of ketoconazole occur in two forms, which are mirror images of each other. These mirror image pairs are referred to as enantiomers. Single enantiomer drugs may offer safety and efficacy advantages because one of the enantiomer

versions can have safety issues or be less effective in treatment of the disorder or disease. The 505(b)(2) regulatory approval pathway allows companies developing drug products to rely in part on FDA conclusions of safety and effectiveness from studies that were not conducted by or for the applicant. Because approval can rest in part on data already accepted by the FDA or otherwise publicly available, an abbreviated and reduced development program may be possible. We are currently conducting a pivotal Phase 3 clinical trial for COR-003 and expect to report top-line data from this trial in the first half of 2017 and file applications for regulatory approval in the second half of 2017.

- *COR-004, a second-generation antisense oligonucleotide, in Phase 2 clinical development for the treatment of acromegaly.* Acromegaly is a rare endocrine disorder that most commonly results from a benign tumor of the pituitary gland, leading to excess production of growth hormone, or GH, and insulin-like growth factor 1, or IGF-1, a key regulator of growth and metabolism. COR-004 has a novel mechanism of action targeting human GH receptor messenger RNA, or GHR mRNA, a molecule that is necessary for the synthesis of GHR protein. Currently, somatostatin analogs, or SSAs, are the most commonly used drug therapy for the treatment of patients with acromegaly. Up to one-half of treated patients do not adequately respond to SSAs and need alternative or adjunctive drug therapies. The novel mechanism of action of COR-004 may result in a differentiated safety and efficacy profile as compared to pegvisomant, the most common drug therapy used as an alternative to or in combination with SSAs. In contrast to daily administration of pegvisomant, we intend to develop COR-004 for once- or twice-weekly administration, potentially leading to improved patient compliance. In addition, we plan to develop COR-004 to be packaged in pre-filled syringes, eliminating the need for reconstitution, in contrast to most other drug therapies for acromegaly. We intend to seek orphan drug designation for COR-004 from the FDA and the EMA. Following a planned pre-Investigational New Drug, or IND, consultation with the FDA in the second half of 2015, we intend to file an IND for COR-004 in the United States and begin a multinational development program to support regulatory approval in the United States and subsequently the European Union.
- *COR-005, a novel SSA, in Phase 2 clinical development for the treatment of acromegaly.* Based on the differentiated activation pattern of COR-005 to somatostatin receptor subtypes, or SSTRs, and preclinical and clinical data, we believe that COR-005 may offer an improved efficacy and safety profile relative to existing drug therapies for acromegaly. COR-005 has been granted orphan drug designation by the FDA and the EMA. Following a planned consultation with the FDA and EMA in the first half of 2016, we intend to file an IND for COR-005 in the United States and begin a multinational development program to support regulatory approval in the United States and European Union.

Since the introduction of our new management team beginning in August 2014, we have established a rare disease, franchise-based business model focused on expansion through a disciplined in-licensing and acquisition strategy. In pursuit of our growth strategy, we have raised over \$70 million since December 2014 from leading life sciences investors, including RA Capital, New Enterprise Associates, Broadfin Capital, HealthCap, Longwood Capital, TVM Capital and Granite Point Capital. Leveraging this capital and our experience in sourcing, selecting, in-licensing and acquiring product candidates, we were successful in augmenting our rare endocrine franchise by adding COR-004 and COR-005 to our product pipeline. We believe that these clinical product candidates, if successful, will benefit from significant development and commercial synergies with our lead product candidate, COR-003, because both Cushing's disease and acromegaly are typically caused by benign pituitary tumors and are mainly treated by pituitary endocrinologists. Given the concentrated specialty prescriber base for these indications, we plan to create a sales force of approximately 30 representatives in each of the United States and the European Union to market our endocrine franchise product candidates, if

approved. In addition, we believe the development of two product candidates with different mechanisms of action to treat acromegaly may potentially enable us to address the broad acromegaly patient population requiring drug therapy.

Our Strategy

Our goal is to transform the lives of patients by building a leading franchise-based, commercially oriented biopharmaceutical company addressing rare diseases with significant unmet medical needs. We are focused on developing, in-licensing, acquiring and eventually commercializing products and product candidates that target rare diseases across several complementary therapeutic areas.

To achieve our goal, we are pursuing the following strategies:

- ***Focus on rare diseases.*** We are developing treatments for rare diseases, initially endogenous Cushing's syndrome and acromegaly. Rare diseases typically have a high unmet need for innovative treatment options. Drug development for the treatment of rare diseases often requires smaller clinical trials and has the potential for accelerated regulatory review. Product candidates focused on rare diseases also often qualify for orphan drug designation, which in the United States provides for seven years of market exclusivity and in the European Union provides for 10 years of market exclusivity after regulatory approval has been granted. In addition, given the well-identified and concentrated prescriber base addressing our target markets, we believe we can use a small, focused sales force to effectively promote our products in key geographies. We believe these characteristics enable more efficient resource allocation.
- ***Independently commercialize products in the United States and the European Union.*** We intend to independently commercialize our rare disease product candidates, if approved, in the United States and the European Union, and selectively in other key global markets. Given the concentrated specialty prescriber base, we plan to create a sales force of approximately 30 representatives in each of the United States and the European Union to market our rare endocrine disease product candidates, if approved. We believe that our ability to execute on this strategy is enhanced by the significant prior commercial experience of key members of our management team. Prior to joining our company, members of our management team were involved in the launch or commercialization of over 20 pharmaceutical products.
- ***Expand our portfolio through a disciplined in-licensing and acquisition strategy.*** We plan to source new product candidates by in-licensing or acquiring them. Our management team seeks to mitigate the potential risks of this strategy by adhering to our disciplined criteria of focusing on in-licensing or acquisition opportunities of products that are already commercially available or that have human clinical data that we believe suggest a high probability of success for development progression and an attractive potential return on investment. As a result of our management team's experience in sourcing, selecting, in-licensing and acquiring product candidates, we were successful in augmenting our rare endocrine franchise by adding COR-004 and COR-005 to our product pipeline.
- ***Utilize a franchise model built on rare disease therapeutic areas.*** We intend to build our company by creating franchises in areas where there is a significant commercial opportunity. We seek to in-license and acquire products and product candidates that target rare diseases in therapeutically aligned franchises. We believe that complementary products and product candidates will allow us to significantly leverage our expertise as well as our development and commercial infrastructure. For example, our product candidates for the treatment of

endogenous Cushing's syndrome and acromegaly, if approved, will serve as the basis for our rare endocrine franchise.

- ***Expand indications of products and product candidates within our franchises.*** In addition to identifying products and product candidates that can form the basis of new rare disease franchises, we also intend to leverage opportunities to develop potential products and product candidates for additional indications within their respective therapeutic franchises. We believe that this approach will enable us to maximize our commercial potential by further leveraging our existing resources and expertise.

Recent Developments

On May 13, 2015, we entered into an exclusive license agreement with Antisense Therapeutics Limited, or Antisense Therapeutics, that provides us with development and commercialization rights to Antisense Therapeutics' product candidate, ATL1103, for endocrinology applications. We refer to this product candidate as COR-004. Under the terms of the agreement, we paid Antisense Therapeutics an initial upfront license fee of \$3.0 million in cash, and we also invested \$2.0 million in Antisense Therapeutics equity. We may become obligated to make additional payments, contingent upon achieving specific development and commercialization milestones, of up to \$105.0 million over the lifetime of the agreement. We may also be required to make royalty payments based on a percentage, ranging from the mid-single digits to the mid-teens, of net sales of COR-004, if approved. We will be responsible for the future clinical development of COR-004 in endocrinology applications and for the funding of associated future development, regulatory and drug manufacture costs. Antisense Therapeutics will retain commercialization rights for COR-004 in endocrinology applications in Australia and New Zealand as well as worldwide rights for COR-004 in indications other than endocrinology, and may utilize any new COR-004 data generated by us in pursuing these other indications, subject to specified terms and conditions set forth in our license agreement with Antisense Therapeutics.

On June 29 and 30, 2015, we raised \$33.2 million in aggregate gross proceeds in a private placement of common shares, the proceeds of which we expect to use primarily for the continued development of COR-003, along with the planned development of our two new programs, COR-004 and COR-005, and for general corporate purposes. The subscription price was \$14.54 per share and we issued 2,284,414 new shares to the investors. The investors in this transaction included RA Capital, New Enterprise Associates, Broadfin Capital, HealthCap, Longwood Capital, TVM Capital and Granite Point Capital.

On June 30, 2015, we acquired from Aspireo Pharmaceuticals Ltd., an Israeli company, its product candidate, DG3173. We refer to this product candidate as COR-005. Under the terms of the acquisition agreement, we issued to Aspireo Pharmaceuticals 2,062,677 common shares, which had a value of \$33.2 million on June 30, 2015. In connection with this acquisition, we made a payment to the Office of the Chief Scientist of the Israeli Ministry of Economy, or OCS, in the amount of \$3.0 million, which represents the repayment of amounts previously granted by OCS to Aspireo Pharmaceuticals, plus interest, that were used in support of research and development conducted by Aspireo Pharmaceuticals for the development of DG3173.

On September 4, 2015, we changed our name from "Cortendo plc" to "Strongbridge Biopharma plc."

Effective September 8, 2015, we settled a share exchange offer pursuant to which holders of 99.449% of the outstanding shares of Cortendo AB tendered their shares in exchange for beneficial interests in ordinary shares of Strongbridge Biopharma plc in the form of depositary receipts and non-accredited holders of Cortendo AB shares located within the United States, representing 0.133% of the outstanding shares of Cortendo AB, agreed to exchange their shares for cash, which cash settlement

occurred on September 14, 2015. Immediately following the settlement of the exchange offer, we effected a 1-for-11 reverse stock split of our outstanding ordinary shares (including the beneficial interests in such shares in the form of depositary receipts).

The information contained in this prospectus gives effect to the closing of these transactions.

Risks Associated with Our Business

Our business is subject to a number of risks of which you should be aware before making an investment decision. These risks are discussed more fully in the “Risk Factors” section of this prospectus immediately following this prospectus summary. These risks include, but are not limited to, the following:

- We are a development-stage biopharmaceutical company and have a limited operating history on which to assess our business, have incurred significant losses over the last several years, and anticipate that we will continue to incur losses for the foreseeable future.
- We have never generated any revenue from product sales and may never be profitable.
- We may not be successful in executing our growth strategy or our growth strategy may not deliver the anticipated results.
- If we acquire other businesses or in-license or acquire other product candidates and are unable to integrate them successfully, our financial performance could suffer.
- We are highly dependent on our key personnel, including our president and chief executive officer, as well as our ability to recruit, retain and motivate additional qualified personnel.
- We and our independent registered public accounting firm have identified a material weakness in our internal control over financial reporting, which could make it difficult to maintain an effective system of internal control over financial reporting, harm investor confidence in our company and affect the value of our ordinary shares.
- We depend entirely on the success of a limited number of product candidates, which are still in preclinical or clinical development. If we do not obtain regulatory approval for and successfully commercialize one or more of our product candidates, or we experience significant delays in doing so, we may never become profitable.
- Clinical trials are very expensive, time consuming, difficult to design and implement, and involve uncertain outcomes. Furthermore, results of earlier studies and trials may not be predictive of results of future trials.
- We have never commercialized a product candidate and we may lack the necessary expertise, personnel and resources to successfully commercialize any of our products that receive regulatory approval on our own or together with suitable partners.
- We operate in a highly competitive and rapidly changing industry, which may result in our competitors discovering, developing or commercializing competing products before or more successfully than we do, or our entering a market in which a competitor has commercialized an established competing product, and we may not be successful in competing with them.
- If we or our licensors are unable to obtain and maintain effective patent rights for our technologies, product candidates or any future product candidates, or if the scope of the patent rights obtained is not sufficiently broad, we may not be able to compete effectively in our markets.

- Even if one or more of our product candidates obtains regulatory approval, we will be subject to ongoing obligations and continued regulatory requirements, which may result in significant additional expense.
- We expect to be classified as a passive foreign investment company for U.S. income tax purposes, and our U.S. shareholders may suffer adverse tax consequences as a result.

Corporate Information

Strongbridge Biopharma plc, an Irish public limited company, was established on May 26, 2015 under the name Cortendo plc. On September 4, 2015, Cortendo plc changed its name to Strongbridge Biopharma plc. Our ordinary shares are currently quoted on the NOTC A-list in Norway.

Cortendo AB, a company organized under the laws of Sweden, was established in October 1996 under the name Stefan Kronvall Medical AB and registered in Sweden in December 1996 for the purpose of developing medically innovative products for pharmaceutical diagnostics and other health care products. Stefan Kronvall Medical AB changed its name to Cortendo AB in 1997, to Cortendo Invest AB in 2003 and then to Cortendo AB (publ) in 2011. Cortendo AB has three wholly owned subsidiaries, Cortendo Invest AB, a company organized under the laws of Sweden, BioPancreate Inc., a Delaware corporation, and Cortendo Cayman Ltd., an exempted company incorporated in the Cayman Islands.

In order to effect a corporate reorganization in connection with this offering, on September 8, 2015, we settled an exchange offer, which we refer to as the Exchange Offer, pursuant to which holders of 99.449% of the outstanding shares of Cortendo AB exchanged their shares for beneficial interests in ordinary shares of Strongbridge Biopharma plc in the form of depositary receipts on a 1-for-1 basis and non-accredited holders of Cortendo AB shares located within the United States, representing 0.133% of the outstanding shares of Cortendo AB, agreed to exchange their shares for cash, which cash settlement occurred on September 14, 2015. Non-accredited U.S. holders of ordinary shares of Cortendo AB received cash in an amount equivalent to the value of one ordinary share of Strongbridge Biopharma plc for each share of Cortendo AB validly exchanged. Pursuant to individual agreements with the holders of options to purchase shares of Cortendo AB, the outstanding options of Cortendo AB were converted to options to purchase an equivalent number of ordinary shares of Strongbridge Biopharma plc.

We intend to acquire the remaining 0.418% of the outstanding shares of Cortendo AB held by shareholders who declined to participate in the Exchange Offer, pursuant to a process permitted by Swedish law. For additional information on this process, see “Risk Factors—Risks Related to the Offering and Our Ordinary Shares—The Swedish squeeze-out process is a lengthy process to complete and will result in additional costs to us. Any delay in our acquiring full ownership of Cortendo AB could result in increased administrative costs and burdens and could adversely affect our day-to-day operations and the liquidity and market value of our shares.”

Following the settlement of the Exchange Offer, Strongbridge Biopharma plc became the parent of Cortendo AB and its subsidiaries. As a result of the settlement of the Exchange Offer, the historical financial statements of Cortendo AB became, for financial reporting purposes, the historical consolidated financial statements of Strongbridge Biopharma plc and its subsidiaries as a continuation of the predecessor.

Our principal executive offices are located at 900 Northbrook Drive, Suite 200, Trevose, Pennsylvania, 19053 and our telephone number is +1 610-254-9200. For the purposes of Irish law, our registered office is Arthur Cox Building, Earlsfort Terrace, Dublin 2, Ireland.

Our website is *www.strongbridgebio.com*. The information on, or that can be accessed through, our website is not part of and should not be incorporated by reference into this prospectus. We have included our website address as an inactive textual reference only.

Solely for convenience, the trademarks and trade names in this prospectus are referred to without the ® and ™ symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. The trademarks, trade names and service marks appearing in this prospectus are the property of their respective owners.

Implications of Being an “Emerging Growth Company”

We qualify as an “emerging growth company,” as defined in the Jumpstart our Business Startups Act of 2012, or the JOBS Act. An emerging growth company may take advantage of specified reduced reporting and regulatory requirements in contrast to those otherwise applicable generally to public companies. These provisions include:

- the requirement to have only two years of audited financial statements and only two years of related Management’s Discussion and Analysis of Financial Condition and Results of Operations disclosure; and
- exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting pursuant to Section 404 the Sarbanes-Oxley Act of 2002.

We may take advantage of these reduced reporting and other regulatory requirements for up to five years or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company if we have more than \$1.0 billion in annual revenue, have more than \$700 million in market value of our ordinary shares held by non-affiliates or issue more than \$1.0 billion of non-convertible debt over a three-year period. In addition, the JOBS Act provides that an emerging growth company may delay adopting new or revised accounting standards until those standards apply to private companies. We have irrevocably elected not to avail ourselves of this delayed adoption of new or revised accounting standards and, therefore, we will be subject to the same new or revised accounting standards as public companies that are not emerging growth companies. If we choose to take advantage of any of these reduced reporting burdens, the information that we provide shareholders may be different than you might get from other public companies.

Implications of Being a Foreign Private Issuer

Upon consummation of this offering, we will report under the Securities Exchange Act of 1934, as amended, or the Exchange Act, as a non-U.S. company with foreign private issuer status. Even after we no longer qualify as an emerging growth company, as long as we qualify as a foreign private issuer under the Exchange Act, we will be exempt from certain provisions of the Exchange Act that are applicable to U.S. domestic public companies, including:

- the sections of the Exchange Act regulating the solicitation of proxies, consents or authorizations in respect of a security registered under the Exchange Act;
- the sections of the Exchange Act requiring insiders to file public reports of their stock ownership and trading activities and liability for insiders who profit from trades made in a short period of time; and
- the rules under the Exchange Act requiring the filing with the Securities and Exchange Commission of quarterly reports on Form 10-Q containing unaudited financial and other specified information, or current reports on Form 8-K upon the occurrence of specified significant events.

We intend to take advantage of these exemptions as a foreign private issuer.

The Offering

Ordinary shares offered by us 2,500,000 ordinary shares

Ordinary shares to be outstanding after this offering 21,205,382 ordinary shares

Option to purchase additional ordinary shares We have granted the underwriters an option, exercisable within 30 days from the date of this prospectus, to purchase up to 375,000 additional ordinary shares.

Use of proceeds We estimate that the net proceeds to us from this offering will be approximately \$19.3 million, after deducting the underwriting discount and estimated offering expenses payable by us. We intend to use the net proceeds from this offering, together with cash and cash equivalents on hand, to fund external research and development expenses for COR-003 for the treatment of endogenous Cushing's syndrome; to fund external research and development expenses for COR-004 for the treatment of acromegaly; to fund external research and development expenses for COR-005 for the treatment of acromegaly; and for working capital, general and administrative expenses, internal research and development expenses, and other general corporate purposes, including pre-commercial activities, potential in-licenses and potential acquisitions. See "Use of Proceeds."

Risk factors See "Risk Factors" and other information included in this prospectus for a discussion of factors that you should consider carefully before deciding to invest in our ordinary shares.

Symbol on The NASDAQ Global Select Market Our ordinary shares have been approved for listing on The NASDAQ Global Select Market under the symbol "SBBP"

Certain of our existing shareholders who beneficially own more than 5% of our ordinary shares and their affiliates have indicated an interest in purchasing up to an aggregate of \$20.0 million of our ordinary shares in this offering at the initial public offering price per share. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters may determine to sell more, less or no shares in this offering to any of these entities, or any of these entities may determine to purchase more, less or no shares in this offering. The underwriters will receive the same underwriting discount on any ordinary shares purchased by these entities as they will on any other shares sold to the public in this offering.

The number of our ordinary shares to be outstanding immediately following the completion of this offering is based on 18,705,382 ordinary shares outstanding as of October 14, 2015, and excludes:

- 2,002,593 ordinary shares issuable upon the exercise of stock options outstanding as of June 30, 2015, with a weighted-average exercise price of \$12.40 per ordinary share;
- 127,363 ordinary shares issuable upon the exercise of stock options that were awarded to our non-employee directors, contingent upon the pricing of this offering, under our new Non-Employee Director Equity Compensation Plan, at an exercise price equal to the higher of the initial public offering price per ordinary share and the closing price of our ordinary

shares on the NOTC on September 22, 2015, which was NOK 145 per ordinary share, equivalent to a price of \$17.55 per share, assuming the exchange rate of NOK 8.2604 per U.S. dollar on September 22, 2015;

- 218,091 ordinary shares reserved for future issuance under our Non-Employee Director Equity Compensation Plan; and
- 1,081,818 ordinary shares reserved for future issuance under our 2015 equity incentive plan.

Unless otherwise indicated, all information contained in this prospectus assumes and gives effect to:

- settlement of the Exchange Offer on September 8, 2015;
- a 1-for-11 reverse stock split of our ordinary shares that we effected on September 8, 2015 immediately following the settlement of the Exchange Offer;
- no exercise of the options described above; and
- no exercise of the underwriters' option to purchase up to 375,000 additional ordinary shares.

Summary Consolidated Financial Data

The following tables set forth a summary of our consolidated financial data. We have derived the consolidated statement of operations data for the years ended December 31, 2013 and 2014 and the balance sheet data as of December 31, 2014 from our consolidated audited financial statements. The consolidated statement of operations data for the six months ended June 30, 2014 and June 30, 2015 and the consolidated balance sheet data as of June 30, 2015 have been derived from our unaudited consolidated financial statements included elsewhere in this prospectus. You should read this data together with the consolidated financial statements and related notes appearing elsewhere in this prospectus and the section in this prospectus titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations.” The historical results are not necessarily indicative of the results to be expected for any future periods and results of interim periods are not necessarily indicative of the results for the entire year.

We have prepared the unaudited consolidated financial information set forth below on the same basis as our audited consolidated financial statements and have included, in the opinion of management, all adjustments, consisting only of normal recurring adjustments, necessary for a fair presentation of the financial information as of and for the periods presented. Our audited consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States, or U.S. GAAP, and are presented in U.S. dollars except where otherwise indicated.

Strongbridge Biopharma plc became the parent company of Cortendo AB pursuant to the settlement of the Exchange Offer, and for financial reporting purposes the historical consolidated financial statements of Cortendo AB became the historical consolidated financial statements of Strongbridge Biopharma plc and its subsidiaries as a continuation of the predecessor.

	Year Ended December 31,		Six Months Ended June 30,	
	2013	2014	2014	2015
	(in thousands, except share and per share data)			
Consolidated Statement of Operations Data:				
Operating expenses:				
Research and development	\$ 2,534	\$ 5,844	\$ 2,460	\$ 10,218
General and administrative	2,658	4,588	1,298	12,620
Total operating expenses	5,192	10,432	3,758	22,838
Operating loss	(5,192)	(10,432)	(3,758)	(22,838)
Other income (expense), net:				
Foreign exchange loss	(570)	(204)	165	(314)
Other income, net	282	486	166	(543)
Total other income (expense), net	(288)	282	331	(857)
Loss before income taxes	(5,480)	(10,150)	(3,427)	(23,695)
Income tax benefit	93	480	225	178
Net loss	(5,387)	(9,670)	(3,202)	(23,517)
Net loss attributable to non-controlling interest	92	—	—	—
Net loss attributable to Strongbridge	<u>\$ (5,295)</u>	<u>\$ (9,670)</u>	<u>\$ (3,202)</u>	<u>\$ (23,517)</u>
Net loss attributable to common shareholders, basic and diluted	<u>\$ (5,295)</u>	<u>\$ (9,670)</u>	<u>\$ (3,202)</u>	<u>\$ (23,517)</u>
Net loss per share attributable to common shareholders, basic and diluted ⁽¹⁾	<u>\$ (0.88)</u>	<u>\$ (1.20)</u>	<u>\$ (0.40)</u>	<u>\$ (1.75)</u>
Weighted-average shares used in computing net loss per share attributable to common shareholders, basic and diluted	<u>6,017,895</u>	<u>8,043,175</u>	<u>7,939,608</u>	<u>13,433,712</u>
Pro forma net loss per share attributable to common shareholders, basic and diluted ⁽²⁾		<u>\$ (0.96)</u>		<u>\$ (1.52)</u>
Weighted-average shares used in computing pro forma net loss per share attributable to common shareholders, basic and diluted ⁽²⁾		<u>10,105,852</u>		<u>15,496,389</u>

- (1) See note 2 to our unaudited and audited consolidated financial statements included elsewhere in this prospectus for an explanation of the method used to calculate basic and diluted net loss per share attributable to common shareholders and basic and diluted weighted-average shares outstanding used to calculate the per share data.
- (2) These amounts give effect to the pro forma adjustments detailed on page 12.

The following table sets forth summary balance sheet data as of June 30, 2015:

- on an actual basis;
- on a pro forma basis to give effect to the settlement of the Exchange Offer, including the payment of cash for shares of Cortendo AB held by non-accredited U.S. holders; and
- on a pro forma as adjusted basis to give further effect to our issuance and sale of 2,500,000 ordinary shares in this offering at the initial public offering price of \$10.00 per share, after deducting the underwriting discount and estimated offering expenses payable by us.

	<u>As of June 30, 2015</u>		
	<u>Actual</u>	<u>Pro Forma</u>	<u>Pro Forma As Adjusted</u>
	(in thousands)		
Consolidated Balance Sheet Data:			
Cash and cash equivalents	\$ 54,387	\$ 53,975	\$ 73,227
Total assets	100,912	100,500	119,752
Total liabilities	13,626	13,626	13,626
Total shareholders' equity	87,286	86,874	106,126

RISK FACTORS

Investing in our ordinary shares involves a high degree of risk. You should carefully consider the risks and uncertainties described below, as well as the other information in this prospectus, before investing in our ordinary shares. Our business, financial condition or results of operations could be materially and adversely affected if any of these risks occurs and, as a result, the market price of our ordinary shares could decline and you could lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may have similar adverse effects on us.

Risks Related to Our Being a Development-Stage Company

We are a development-stage biopharmaceutical company and have a limited operating history on which to assess our business, have incurred significant losses over the last several years, and anticipate that we will continue to incur losses for the foreseeable future.

We are a development-stage biopharmaceutical company with a limited operating history. We have not yet demonstrated an ability to successfully complete a large-scale, pivotal clinical trial, obtain regulatory approval or manufacture and commercialize a product candidate. Consequently, we have no meaningful commercial operations upon which to evaluate our business and predictions about our future success or viability may not be as accurate as they could be if we had a history of successfully developing and commercializing pharmaceutical products.

Since inception, we have incurred significant operating losses. Our net loss was \$5.4 million and \$9.7 million for the years ended December 31, 2013 and 2014, respectively and \$23.5 million for the six months ended June 30, 2015. As of December 31, 2014, we had an accumulated deficit of \$37.2 million and an accumulated deficit of \$60.7 million for the six months ended June 30, 2015. We have devoted substantially all of our financial resources to identifying, in-licensing, acquiring and developing our product candidates, including conducting clinical trials and providing general and administrative support for these operations to build our business infrastructure.

To date, we have financed our operations primarily through private placements of equity securities. The amount of our future net losses will depend, in part, on the rate of our future expenditures and our ability to obtain funding through equity or debt financings, strategic collaborations or grants. To become and remain profitable, we must develop and eventually commercialize one or more of our product candidates with significant market potential. Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. It may be several years, if ever, before we receive regulatory approval and have a product candidate approved for commercialization. Even if we obtain regulatory approval to market a product candidate, our future revenue will depend upon the size of any markets in which our product candidates may receive approval and our ability to achieve market acceptance and adequate market share for our product candidates in those markets. Further, because the potential markets in which our product candidates may ultimately receive regulatory approval are very small, we may never become profitable despite obtaining such market share and acceptance of our product candidates.

We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. We anticipate that our expenses will increase substantially if and as we:

- continue research and nonclinical and clinical development of our product candidates, including advancing our programs from preclinical development into clinical trials and increasing the number and size of our current clinical trials and preclinical studies;
- seek to identify, assess, in-license, acquire and develop additional product candidates;
- change or add manufacturers or suppliers;

- seek regulatory approvals for our product candidates that successfully complete clinical trials;
- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain regulatory approval;
- make up-front, milestone or other payments under any of our license agreements;
- seek to maintain, protect and expand our intellectual property portfolio;
- seek to attract and retain skilled personnel;
- create additional infrastructure to support our operations as a U.S. listed company and our product development and planned future commercialization efforts; and
- experience any delays or encounter issues with any of the above, including, but not limited to, failed preclinical studies or clinical trials, complex results, safety issues or other regulatory challenges that may require either longer follow-up of existing preclinical studies or clinical trials or limitation of additional preclinical studies or clinical trials in order to pursue regulatory approval.

Further, the net losses we incur may fluctuate significantly from quarter-to-quarter and year-to-year, such that a period-to-period comparison of our results of operations may not be a good indication of our future performance. Moreover, if we incur substantial losses, we could be liquidated, and the value of our shares might be significantly reduced or the shares might be of no value.

We have never generated any revenue from product sales and may never be profitable.

We have no products approved for commercialization and have never generated any revenue from product sales. We will not generate revenue from product sales unless and until we successfully complete the development of, obtain regulatory approval for and commercialize one or more of our product candidates. Our ability to generate future revenue from product sales depends heavily on our success in many areas, including, but not limited to:

- completing research, preclinical or clinical development, as applicable, of our product candidates, including successfully completing clinical trials of our product candidates;
- integrating product candidates that we in-license or acquire, as well as completing research, formulation and process development, and preclinical or clinical development, as applicable, of those product candidates, including successfully completing clinical trials of those product candidates;
- obtaining regulatory approval our product candidates;
- incurring additional costs as we advance our product candidates;
- developing a sustainable and scalable manufacturing process for our product candidates, if approved;
- maintaining supply and manufacturing relationships with third parties that can conduct the manufacturing process development and provide adequate, in amount and quality, products to support clinical development and the market demand for our product candidates, if approved;
- developing a commercial organization and launching and commercializing product candidates for which we obtain regulatory approval, either directly or with a collaborator or distributor;
- obtaining market acceptance of our product candidates as viable treatment options;

- addressing any competing technological and market developments;
- identifying, assessing, in-licensing, acquiring and/or developing new product candidates;
- negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter;
- maintaining, protecting and expanding our portfolio of intellectual property rights, including patents, trade secrets and know-how; and
- attracting, hiring and retaining qualified personnel.

Given the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. Our expenses could increase beyond expectations if we are required by the FDA or the EMA, or any comparable foreign regulatory agency, to perform nonclinical and preclinical studies or clinical trials in addition to those that we currently anticipate.

Even if one or more of the product candidates that we develop is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate. Further, our revenue will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval, the accepted price for the product, the ability to obtain coverage and adequate reimbursement, and whether we own the commercial rights for that territory. If the number of our addressable patients is not as significant as we estimate, the indication approved by regulatory authorities is narrower than we expect, or the treatment population is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of our product candidates. If we are not able to generate sufficient revenue from the sale of any approved products, we may never become profitable. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to successfully execute any of the foregoing would decrease the value of our company and could impair our ability to raise capital, expand our business or continue our operations. A decline in the value of our company could cause you to lose all or part of your investment.

Even if this offering is successful, we expect that we will need substantial additional funding before we can expect to complete the development of our product candidates and become profitable from sales of our approved products, if any.

We are currently advancing our product candidates through preclinical and clinical development. Development of our product candidates is expensive, and we expect our research and development expenses to increase in connection with our ongoing activities, particularly as we continue our ongoing trials and initiate new trials of COR-003, COR-004, COR-005 and our other product candidates. Even with the proceeds of this offering, we expect that we will require additional capital to obtain regulatory approval for, and to commercialize, our product candidates, including the making of milestone payments under the terms of our in-license agreement for COR-004.

As of June 30, 2015, our cash and cash equivalents were \$54.4 million. We currently believe that the net proceeds of this offering, together with our existing cash and cash equivalents, will enable us to fund our operating expenses and capital expenditure requirements for at least the next 12 months. However, this estimate is based on assumptions that may prove to be incorrect, our operating plans may change as a result of many factors that may currently be unknown to us, and we may need to seek additional funds sooner than planned. Our future funding requirements will depend on many factors, including, but not limited to:

- the scope, rate of progress, results and cost of our clinical trials, nonclinical testing, formulation, process development and other related activities;

- the cost of manufacturing clinical supplies and establishing commercial supplies of our product candidates, if approved, and any products that we may develop;
- the number and characteristics of product candidates that we pursue, including any additional product candidates we may in-license or acquire;
- the cost of filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights;
- the cost of defending potential intellectual property disputes, including patent infringement actions brought by third parties against us or our product candidates;
- the cost, timing and outcomes of regulatory approvals;
- the cost and timing of establishing sales, marketing and distribution capabilities; and
- the terms and timing of any collaborative, licensing and other arrangements that we may establish, including any required milestone and royalty payments thereunder.

Any additional fundraising efforts may divert our management from their day-to-day activities, which may compromise our ability to develop and commercialize our product candidates, if approved. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. Moreover, the terms of any financing may adversely affect the holdings or the rights of our shareholders and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our ordinary shares to decline.

If we are unable to obtain funding on a timely basis, we may be required to significantly curtail, delay or discontinue one or more of our research or development programs or the commercialization of any product candidates, if approved, or be unable to expand our operations or otherwise capitalize on our business opportunities, as desired.

Raising additional capital may cause dilution to our shareholders, restrict our operations or require us to relinquish rights to our intellectual property or future revenue streams.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings, grants, and license and development agreements in connection with any collaborations. We do not have any committed external source of funds. In the event we seek additional funds, we may raise additional capital through the sale of equity or convertible debt securities. In such an event, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a holder of our ordinary shares. Debt financing, if available, could result in increased fixed payment obligations and may involve agreements that include restrictive covenants, such as limitations on our ability to incur additional debt, make capital expenditures, acquire, sell or license intellectual property rights or declare dividends, and other operating restrictions that could hurt our ability to conduct our business.

Further, if we raise additional funds through collaborations, strategic alliances, or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our intellectual property or future revenue streams. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts, or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

We may not be successful in executing our growth strategy or our growth strategy may not deliver the anticipated results.

We plan to source new product candidates that are complementary to our existing product candidates by in-licensing or acquiring them from other companies or academic institutions. If we are unable to identify, in-license or acquire and integrate product candidates in accordance with this strategy, our ability to pursue our growth strategy would be compromised.

Research programs and business development efforts to identify new product candidates require substantial technical, financial and human resources. We may focus our efforts and resources on potential programs or product candidates that ultimately prove to be unsuccessful. Our research programs, business development efforts or licensing attempts may fail to yield additional complementary or successful product candidates for clinical development and commercialization for a number of reasons, including, but not limited to, the following:

- our research or business development methodology or search criteria and process may be unsuccessful in identifying potential product candidates with a high probability of success for development progression;
- we may not be able or willing to assemble sufficient resources or expertise to in-license, acquire or discover additional product candidates;
- for product candidates we seek to in-license or acquire, we may not be able to agree to acceptable terms with the licensor or owner of those product candidates;
- our product candidates may not succeed in preclinical studies or clinical trials;
- we may not succeed in formulation or process development;
- our product candidates may be shown to have harmful side effects or may have other characteristics that may make the products unmarketable or unlikely to receive regulatory approval;
- competitors may develop alternatives that render our product candidates obsolete or less attractive;
- product candidates that we develop may be covered by third parties' patents or other exclusive rights;
- product candidates that we develop may not allow us to leverage our expertise and our development and commercial infrastructure as currently expected;
- the market for a product candidate may change during our program so that such a product may become unreasonable to continue to develop;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and
- a product candidate may not be accepted as safe and effective by patients, the medical community or third-party payors.

If any of these events occurs, we may not be successful in executing our growth strategy or our growth strategy may not deliver the anticipated results.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

We have limited financial and managerial resources. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

If we acquire other businesses or in-license or acquire other product candidates and are unable to integrate them successfully, our financial performance could suffer.

If we are presented with appropriate opportunities, we may acquire other businesses. We have had limited experience integrating other businesses or product candidates, or in-licensing or acquiring other product candidates. Since our formation in 1996, we have in-licensed or acquired three product candidates: COR-004, COR-005 and BP-2001. The in-license of COR-004 and the acquisition of COR-005 occurred recently and we are still in the early stages of integrating them into our business. The integration process following these or any future transactions may produce unforeseen operating difficulties and expenditures, and may absorb significant management attention that would otherwise be directed to the ongoing development of our business. Also, in any future in-licensing or acquisition transactions, we may issue shares of stock that would result in dilution to existing shareholders, incur debt, assume contingent liabilities or create additional expenses related to amortizing intangible assets, any of which might harm our financial results and cause our stock price to decline. Any financing we might need for future transactions may be available to us only on terms that restrict our business or impose costs that reduce our net income.

We are highly dependent on our key personnel, including our president and chief executive officer, as well as our ability to recruit, retain and motivate additional qualified personnel.

We are highly dependent on Matthew Pauls, our President and Chief Executive Officer, and Dr. Ruth Thieroff-Ekerdt, our Chief Medical Officer. Some members of our management team, including Matthew Pauls, have only been our employees since September 2014. As a result, they have limited experience working for us and working together as a team. Any member of management or employee can terminate his or her relationship with us at any time. Although we have included non-compete provisions in their respective employment or consulting agreements, as the case may be, such arrangements might not be sufficient for the purpose of preventing such key personnel from entering into agreements with any of our competitors. The inability to recruit and retain qualified personnel, or the loss of Mr. Pauls or Dr. Thieroff-Ekerdt could result in competitive harm as we could experience delays in reaching our in-licensing, acquisition, development and commercialization objectives.

We also depend substantially on highly qualified managerial, sales and technical personnel who are difficult to hire and retain. There is currently a shortage of skilled personnel in our industry, which is likely to continue. As a result, competition for skilled personnel is intense and the turnover rate can be high. We may not be able to attract and retain personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for individuals with similar skill sets. In

addition, failure to succeed in preclinical studies or clinical trials may make it more challenging to recruit and retain qualified personnel. Recruiting and retaining other qualified employees, consultants and advisors for our business, including scientific and technical personnel, will be critical to our success.

We expect to expand our organization, and we may experience difficulties in managing this growth, which could disrupt our operations.

As of June 30, 2015, we had 13 full-time employees. As our development, commercialization, in-licensing and acquisition plans and strategies develop, and as we advance the preclinical and clinical development of our product candidates, we expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of managerial, operational, sales, marketing, financial, legal and other resources. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities, and continue to recruit and train additional qualified personnel. Our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. Due to our limited financial resources, we may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the in-licensing, acquisition and development of additional product candidates. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate or grow revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to compete effectively will depend, in part, on our ability to effectively manage any future growth.

We and our independent registered public accounting firm identified a material weakness in our internal control over financial reporting, and our inability sufficiently to remediate this weakness may reduce the reliability of our financial reporting, harm investor confidence in our company and affect the value of our ordinary shares.

In connection with the audits of our 2013 and 2014 financial statements, which were completed concurrently, we and our independent registered public accounting firm identified a material weakness, primarily related to the lack of sufficient and skilled resources with knowledge of U.S. GAAP and SEC reporting requirements to ensure that accurate financial statements could have been prepared and reviewed on a timely basis for annual reporting purposes. We determined that we had insufficient financial statement close processes and procedures, including with respect to account reconciliations and the resolution of complex accounting issues involving significant judgment and estimates. We may be unable to improve our internal control over financial reporting sufficiently to remediate this material weakness and, consequently, to maintain an effective system of internal control over financial reporting. This may reduce the reliability of our financial reporting, harm investor confidence in our company and affect the value of our ordinary shares.

Under standards established by the Public Company Accounting Oversight Board, or PCAOB, a material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected and corrected on a timely basis.

While we are taking steps to remediate this weakness, we cannot at this time estimate how long it will take, and our initiatives may not prove to be successful in remediating the material weakness. If we are unable to successfully remediate these material weaknesses, and if we are unable to produce accurate and timely financial statements, investor confidence in our financial statements could be reduced, our share price may be adversely affected and we may be unable to maintain compliance with applicable SEC requirements.

Effective internal control over financial reporting is necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, Section 404 will require us to evaluate and report on our internal control over financial reporting beginning with our second Annual Report on Form 20-F expected to be for the year ending December 31, 2016. This assessment will need to include disclosure of any material weaknesses in our internal control over financial reporting identified by our management. Any weaknesses in our internal control over financial reporting may adversely affect our ability to maintain required disclosure controls and procedures. We may not be able to complete our evaluation, testing and any required remediation in a timely fashion. During the evaluation and testing processes, if we identify one or more material weaknesses in our internal control over financial reporting, we will be unable to conclude that our internal control over financial reporting is effective. If we are unable to conclude that our internal control over financial reporting is effective, we could lose investor confidence in the accuracy and completeness of our financial reports, which could have a material adverse effect on the price of our ordinary shares. Our remediation efforts may not enable us to avoid a material weakness in the future.

Our management will be required to assess the effectiveness of our internal controls and financial reporting annually. However, for as long as we are an “emerging growth company” under the JOBS Act, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404. We could be an “emerging growth company” for up to five years. An independent assessment of the effectiveness of our internal control over financial reporting could detect problems that our management’s assessment might not. Undetected material weaknesses in our internal control over financial reporting could lead to financial statement restatements and require us to incur the expense of remediation.

Our business and operations would suffer in the event of system failures.

Our computer systems, as well as those of our clinical research organizations, or CROs, and other contractors and consultants, are vulnerable to damage from computer viruses, unauthorized access, natural disasters, including hurricanes, terrorism, war and telecommunication and electrical failures. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our product development programs. For example, the loss of preclinical study or clinical trial data from completed, ongoing or planned preclinical studies or clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications, or inappropriate disclosure of personal, confidential or proprietary information, we could incur liability and the further development of our product candidates could be delayed.

Risks Related to the Development and Preclinical and Clinical Testing of Our Product Candidates

We depend entirely on the success of a limited number of product candidates, which are still in preclinical or clinical development. If we do not obtain regulatory approval for and successfully commercialize one or more of our product candidates or we experience significant delays in doing so, we may never become profitable.

We currently have no products approved for sale and may never be able to obtain regulatory approval of or commercialize any products. We have invested, and continue to expect to invest, a significant portion of our efforts and financial resources in the development of a limited number of product candidates: COR-003, COR-004 and COR-005, which are still in clinical development. Our ability to generate product revenues, which we do not expect will occur for at least the next several years, if ever, will depend heavily on our successful development and eventual commercialization, if approved, of one or more of our product candidates. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the FDA, EMA or any

comparable foreign regulatory agency, and we may never receive such regulatory approval for any of our product candidates. The success of COR-003, COR-004 and COR-005 will depend on several additional factors, including, but not limited to, the following:

- successfully completing formulation and process development activities;
- successfully completing clinical trials that demonstrate the efficacy and safety of our product candidates;
- acceptance of our product candidates by patients and the medical community;
- a continued acceptable safety profile following approval;
- obtaining and maintaining healthcare coverage and adequate reimbursement; and
- competing effectively with other therapies, including with respect to the sales and marketing of our product candidates, if approved.

Many of these factors are beyond our control, including clinical development, the regulatory submission process, potential threats to our intellectual property rights and changes in the competitive landscape. If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully complete clinical trials or eventually commercialize our product candidates, if approved.

Clinical trials are very expensive, time consuming and difficult to design and implement and involve uncertain outcomes. Furthermore, results of earlier preclinical studies and clinical trials may not be predictive of results of future preclinical studies or clinical trials.

To obtain the requisite regulatory approvals to market and sell any of our product candidates, we must demonstrate through extensive preclinical studies and clinical trials that our products are safe and effective in humans. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies and earlier clinical trials may not be predictive of the results of later-stage clinical trials. For example, the results generated to date in preclinical studies or clinical trials for our product candidates do not ensure that later preclinical studies or clinical trials will demonstrate similar results. Further, we have limited clinical data for each of our product candidates and have not completed Phase 3 clinical trials for any of our product candidates. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. Companies in the biopharmaceutical industry may suffer setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier clinical trials. For example, COR-003 was previously studied for the treatment of type 2 diabetes. In December 2005, prior to the initiation of the first clinical trial by DiObex, our licensee, the FDA placed a clinical hold relating to a safety concern for use of a dosage above 600 mg/day. DiObex modified the clinical trial protocol to limit the highest dose to 600 mg/day, and the clinical hold was lifted by the FDA in February 2006. Furthermore, COR-003 did not demonstrate a reduction in blood glucose levels in a small Phase 2 clinical trial in patients with type 2 diabetes mellitus, the original indication for which it was being developed. We may experience delays in our ongoing or future preclinical studies or clinical trials, and we do not know whether future preclinical studies or clinical trials will begin on time, need to be redesigned, enroll an adequate number of subjects or patients on time or be completed on schedule, if at all. Clinical trials may be delayed, suspended or terminated for a variety of reasons, including delay or failure to:

- obtain authorization from regulators or institutional review boards, or IRBs, to commence a clinical trial at a prospective clinical trial site;

- reach agreements on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- recruit and enroll a sufficient number of patients in clinical trials to ensure adequate statistical power to detect statistically significant treatment effects;
- address any noncompliance with regulatory requirements or safety concerns that arise during the course of a clinical trial;
- have patients complete clinical trials or return for post-treatment follow-up;
- have CROs or other third parties comply with regulatory requirements, adhere to the trial protocol or meet contractual obligations in a timely manner or at all;
- identify a sufficient number of clinical trial sites and initiate them within the planned timelines; and
- manufacture sufficient quantities of the product candidate to complete clinical trials.

Positive or timely results from preclinical or early stage clinical trials do not ensure positive or timely results in late stage clinical trials or regulatory approval by the FDA, EMA or any comparable foreign regulatory agency. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. Preclinical and clinical data are often susceptible to varying interpretations and analyses. Many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain regulatory approval for the product candidates. The FDA, EMA and any comparable foreign regulatory agency have substantial discretion in the approval process and in determining when or whether regulatory approval will be obtained for any of our product candidates. Even if we believe the data collected from clinical trials of our product candidates are promising, such data may not be sufficient to support approval by the FDA, EMA or any comparable foreign regulatory agency.

In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in clinical trial procedures set forth in protocols, differences in the size and type of the patient populations, adherence to the administration regimen and other clinical trial protocols, and the rate of dropout among clinical trial participants. In the case of our late stage clinical product candidates, results may differ in general on the basis of the larger number of clinical trial sites and additional countries involved in Phase 3 clinical trials. Different countries have different standards of care and different levels of access to care for patients, which in part drives the heterogeneity of the patient populations that enroll in our studies.

We have already met with the EMA's Committee for Medicinal Products for Human Use and the FDA regarding the development pathway of COR-003. The FDA recommended, but did not require, a control group in the clinical trial design. We concluded that it was not practical to use any approved drug to serve as an active control in our Phase 3 clinical trial of COR-003. We are using an open-label, single-arm design because in the past the FDA has deemed that the concurrent use of a placebo control as monotherapy is unethical for the treatment of endogenous Cushing's syndrome. In addition, based on our analysis and feedback from experts whom we have consulted, we concluded that it was not practical to use any approved drug to serve as an active control due to the unsuitable mode of action, route of administration and side effect profile of available approved therapies. Studies lacking an active control group are more likely to be subject to unanticipated variability in study results that can potentially lead to flawed conclusions because they do not allow for discrimination of patient outcomes. As a result, even if we achieve the clinical trial's end points, the FDA or other regulatory

authorities could view our study results as potentially biased and may ultimately require that we conduct a randomized, controlled clinical trial of COR-003 in order to obtain approval for commercialization. Unfavorable data from our clinical trials may restrict the potential development and commercialization of COR-003 or lead to the termination of its development.

In addition, we recently in-licensed COR-004 and acquired COR-005 and were not involved in and had no control over the preclinical and clinical development of these product candidates prior to such in-license or acquisition. We may experience difficulties in the transition of these product candidates, which may result in delays in clinical trials as well as problems in our development efforts and regulatory filings, particularly if we do not receive all of the necessary products, information, reports and data for these product candidates in a timely manner. In addition, we are dependent on the prior research and development of COR-004 and COR-005 having been conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, the results of all clinical trials conducted prior to our in-license or acquisition, as the case may be, having been accurately reported and the collected and the data from these clinical trials having been correctly interpreted. These problems could result in increased costs and delays in the development of COR-004 and COR-005, which could hurt our ability to generate future revenues from these product candidates.

The regulatory approval process of the FDA, EMA or any comparable foreign regulatory agency may be lengthy, time consuming and unpredictable.

Our future success is dependent upon our ability to successfully develop, obtain regulatory approval for and then successfully commercialize one or more of our product candidates. Although certain of our employees have prior experience with submitting marketing applications to the FDA, EMA or any comparable foreign regulatory agency, we, as a company, have not submitted such applications for our product candidates. We cannot be certain that any of our product candidates will be successful in clinical trials or receive regulatory approval. Applications for any of our product candidates could fail to receive regulatory approval for many reasons, including, but not limited to, the following:

- the FDA, EMA or any comparable foreign regulatory agency may disagree with the design or implementation of our clinical trials or our interpretation of data from nonclinical trials or clinical trials;
- the population studied in the clinical program may not be sufficiently broad or representative to assure safety in the full population for which we seek approval, including reliance on foreign clinical data;
- the data collected from clinical trials of our product candidates may not be sufficient to support a finding that has statistical significance or clinical meaningfulness or support the submission of a new drug application, or NDA, or other submission, or to obtain regulatory approval in the United States or elsewhere;
- we may be unable to demonstrate to the FDA, EMA or any comparable foreign regulatory agency that a product candidate's risk-benefit ratio for its proposed indication is acceptable;
- the FDA, EMA or any comparable foreign regulatory agency may fail to approve the manufacturing processes, test procedures and specifications or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA, EMA or any comparable foreign regulatory agency may significantly change in a manner rendering our clinical data insufficient for approval.

Any of our current or future product candidates could take a significantly longer time to gain regulatory approval than expected or may never gain regulatory approval. This could delay or eliminate any potential product revenue by delaying or terminating the potential commercialization of our product candidates. For example, although our Phase 3 clinical program for COR-003 has an open-label, single-arm design because a concurrent placebo control as monotherapy was deemed unethical, and an approved drug to serve as active control (monotherapy) or as background therapy (adjunctive therapy) suitable for an international study population was deemed impractical, the FDA has recommended the inclusion of a control group. Therefore, even if we achieve the clinical trial's endpoints, the FDA and other regulatory authorities may ultimately require that we conduct a randomized, controlled clinical trial of COR-003 in order to obtain approval for commercialization.

We intend to seek formal advice and guidance from the FDA and the EMA prior to advancing COR-004 and COR-005 into further studies and pivotal clinical trials. If the feedback we receive is different from what we currently anticipate, this could delay the development and regulatory approval process for these product candidates.

We generally plan to seek regulatory approval to commercialize our product candidates in the United States, the European Union and other key global markets. To obtain regulatory approval in other countries, we must comply with numerous and varying regulatory requirements of such other countries regarding safety, efficacy, chemistry, manufacturing and controls, clinical trials, commercial sales, pricing and distribution of our product candidates. Even if we are successful in obtaining approval in one jurisdiction, we cannot ensure that we will obtain approval in any other jurisdictions. Failure to obtain marketing authorization for our product candidates will result in our being unable to market and sell such products. If we fail to obtain approval in any jurisdiction, the geographic market for our product candidates could be limited. Similarly, regulatory agencies may not approve the labeling claims that are necessary or desirable for the successful commercialization of our product candidates.

If serious adverse, undesirable or unacceptable side effects are identified during the development of our product candidates or following regulatory approval, if any, we may need to abandon our development of such product candidates.

If our product candidates are associated with serious adverse, undesirable or unacceptable side effects, we may need to abandon their development or limit development to certain uses or sub-populations in which such side effects are less prevalent, less severe or more acceptable from a risk-benefit perspective. Many compounds that initially showed promise in preclinical or early stage testing have later been found to cause side effects that restricted their use and prevented further development of the compound for larger indications.

For example, in our clinical trials of COR-003 to date, adverse events have included headache, nausea, back pain, dizziness, diarrhea and liver enzyme elevations. For COR-004 and COR-005, which are both given by subcutaneous injections, adverse events have included injection site reaction such as swelling, itching and pain. In addition, transient and mild elevation of liver enzymes and transient and mild decrease of platelets were observed for COR-004, and headache and gastrointestinal effects such as nausea and diarrhea were observed for COR-005. These adverse events can be dose-dependent and may increase in frequency and severity if we increase the dose to increase efficacy. Occurrence of serious treatment-related side effects could impede clinical trial enrollment, require us to halt the clinical trial, and prevent receipt of regulatory approval from the FDA, EMA or any comparable foreign regulatory agency. They could also adversely affect physician or patient acceptance of our product candidates.

Discovery of previously unknown problems, or increased focus on a known problem, with an approved product may result in restrictions on its permissible uses, including withdrawal of the medicine from the market. Currently, ketoconazole is required to include a "black box" warning on its

label for use as an antifungal related to liver toxicity in the United States. Ketoconazole is the racemic mixture, meaning it contains both mirror image forms of the molecule in a 1:1 ratio, from which we draw our single enantiomer product candidate COR-003. If COR-003 is required to include a similar “black box” warning on its label, it may limit our ability to commercialize the product, if approved.

Additionally, if one or more of our product candidates receives regulatory approval, and we or others later identify undesirable side effects caused by such product(s), a number of potentially significant negative consequences could result, including, but not limited to:

- withdrawal by regulatory authorities of approvals of such product;
- seizure of the product by regulatory authorities;
- recall of the product;
- restrictions on the marketing of the product;
- requirement by regulatory authorities of additional warnings on the label, such as a black box warning;
- requirement that we create a medication guide outlining the risks of such side effects for distribution to patients;
- commitment to expensive additional safety studies prior to launch as a prerequisite of approval by regulatory authorities of such product;
- commitment to expensive post-marketing studies as a prerequisite of approval by regulatory authorities of such product;
- initiation of legal action against us claiming to hold us liable for harm caused to patients; and
- harm to our reputation and resulting harm to physician or patient acceptance of our products.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, financial condition, and results of operations.

We may find it difficult to enroll patients in our clinical trials given the limited number of patients who have the diseases for the treatment of which our product candidates are being studied. Difficulty in enrolling patients in our clinical trials could delay or prevent clinical trials of our product candidates.

Successful and timely completion of clinical trials will require that we enroll a sufficient number of patient candidates. Clinical trials may be subject to delays as a result of patient enrollment taking longer than anticipated or patient withdrawal. Patient enrollment depends on many factors, including the size and nature of the patient population, eligibility criteria for the clinical trial, the proximity of patients to clinical sites, the design of the clinical protocol, the availability of competing clinical trials, the availability of new drugs approved for the indication the clinical trial is investigating, and clinicians’ and patients’ perceptions as to the safety and potential advantages of the product candidate being studied in relation to other available therapies.

Because we are focused on addressing rare diseases, there are limited patient pools from which to draw in order to complete our clinical trials in a timely and cost-effective manner. Delays in the completion of any clinical trial of our product candidates will increase our costs, slow down our product candidate development and approval process, and delay or potentially jeopardize our ability to commence product sales and generate revenue. In addition, many of the factors that may lead to a

delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

We may become exposed to costly and damaging liability claims, either when testing our product candidates in the clinic or at the commercial stage, and our product liability insurance may not cover all damages from such claims.

We are exposed to potential product liability and professional indemnity risks that are inherent in the research, development, manufacturing, marketing, and use of pharmaceutical products. We currently have no products that have been approved for commercial sale. However, the current and future use of product candidates by us in clinical trials, and the sale of any approved products in the future, may expose us to liability claims. These claims might be made by patients that use the product, healthcare providers, pharmaceutical companies, or others selling such products. Any claims against us, regardless of their merit, could be difficult and costly to defend, and could compromise the market acceptance of our product candidates or any prospects for commercialization of our product candidates, if approved.

Although the clinical trial process is designed to identify and assess potential side effects, it is always possible that a drug, even after regulatory approval, may exhibit unforeseen side effects. If any of our product candidates were to cause adverse side effects during clinical trials or after approval of the product candidate, we may be exposed to substantial liabilities. Physicians and patients may not comply with any warnings that identify known potential adverse effects and patients who should not use our product candidates.

We purchase liability insurance in connection with our clinical trials. It is possible that our liabilities could exceed our insurance coverage. We intend to expand our insurance coverage to include the sale of commercial products if we obtain regulatory approval for any of our product candidates. However, we may not be able to maintain insurance coverage at a reasonable cost or obtain insurance coverage that will be adequate to satisfy any liability that may arise. If a successful product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business operations could be impaired.

Risks Related to Commercialization of Our Product Candidates

We have never commercialized a product candidate and we may lack the necessary expertise, personnel and resources to successfully commercialize any of our products that receive regulatory approval on our own or together with suitable partners.

We have never commercialized a product candidate. Our operations to date have been limited to organizing and staffing our company, business planning, raising capital, in-licensing or acquiring our product candidates, identifying potential product candidates and undertaking preclinical studies and clinical trials of our product candidates. We currently have no sales force or marketing or distribution capabilities. To achieve commercial success of our product candidates, if approved, we will have to develop our own sales, marketing and supply capabilities or outsource these activities to a third party.

Factors that may affect our ability to commercialize our product candidates on our own include recruiting and retaining adequate numbers of effective sales and marketing personnel, obtaining access to or persuading adequate numbers of physicians to prescribe our product candidates and other unforeseen costs associated with creating an independent sales and marketing organization. Developing a sales and marketing organization requires significant investment, is time consuming and could delay the launch of our product candidates. We may not be able to build an effective sales and marketing organization in the United States, the European Union or other key global markets. If we are unable to build our own distribution and marketing capabilities or to find suitable partners for the commercialization of our product candidates, we may not generate revenues from them.

We operate in a highly competitive and rapidly changing industry, which may result in our competitors discovering, developing or commercializing competing products before or more successfully than we do, or our entering a market in which a competitor has commercialized an established competing product, and we may not be successful in competing with them.

The development and commercialization of new drug products is highly competitive and subject to significant and rapid technological change. Our success is highly dependent upon our ability to in-license, acquire, develop and obtain regulatory approval for new and innovative drug products on a cost-effective basis and to market them successfully. In doing so, we face and will continue to face intense competition from a variety of businesses, including large, fully integrated, well-established pharmaceutical companies who already possess a large share of the market, specialty pharmaceutical companies and biopharmaceutical companies, academic institutions, government agencies and other private and public research institutions in Europe, the United States and other jurisdictions.

We are currently aware of various companies that are marketing existing drugs that may compete with our product candidates such as Corcept Therapeutics and Novartis. Corcept Therapeutics markets Korlym (mifepristone) in the United States. Korlym is indicated for the control of hyperglycemia secondary to hypercortisolism in patients with endogenous Cushing's syndrome who have type 2 diabetes or glucose intolerance and have failed surgery or are not candidates for surgery. The product has already received regulatory approval from the FDA and was launched in the United States in April 2012. Similarly, Novartis markets Signifor (pasireotide), a somatostatin analog approved for the treatment of adults with Cushing's disease for whom pituitary surgery is not an option or has not been curative. In 2012, Signifor was approved by the EMA for the treatment of Cushing's disease, and was approved by the FDA in December 2012. It is also an approved SSA therapy for the treatment of acromegaly. The product has been marketed in the United Kingdom, Germany and other European countries since 2012, and in the United States since the first half of 2013. Additionally, in 2014, the EMA approved ketoconazole for the treatment of endogenous Cushing's syndrome. Ketoconazole is the most commonly prescribed drug therapy for the treatment of endogenous Cushing's syndrome, even though it is not approved for this use in the United States. Regulatory approval of ketoconazole in the United States for the treatment of endogenous Cushing's syndrome could significantly increase competition for COR-003 due to their similar mechanisms of action.

Other companies acquiring and developing or marketing drug therapies or products for rare diseases include Ipsen, Pfizer, GP Pharma, Italfarmaco, HRA and Chiasma. We anticipate this competition to increase in the future as new companies enter the endocrinology and rare diseases markets. In addition, the health care industry is characterized by rapid technological change, and new product introductions or other technological advancements could make some or all of our products obsolete.

The highly competitive nature of and rapid technological changes in the biotechnology and pharmaceutical industries could render our product candidates or our technology obsolete or non-competitive. Our competitors may, among other things:

- have similar or better product candidates or technologies;
- possess greater financial and human resources as well as supporting clinical data;
- develop and commercialize products that are safer, more effective, less expensive, or more convenient or easier to administer;
- obtain regulatory approval more quickly;
- establish superior proprietary positions;
- have access to greater manufacturing capacity;

- seek patent protection that competes with our product candidates;
- implement more effective approaches to sales and marketing; or
- enter into more advantageous collaborative arrangements for research, development, manufacturing and marketing of products.

The successful commercialization of our product candidates will depend in part on the extent to which governmental authorities and health insurers establish adequate coverage and reimbursement levels and pricing policies.

The successful commercialization of our product candidates, if approved, will depend, in part, on the extent to which coverage and reimbursement for our products or procedures using our products will be available from government and health administration authorities, private health insurers and other third-party payors. To manage healthcare costs, many governments and third-party payors increasingly scrutinize the pricing of new technologies and require greater levels of evidence of favorable clinical outcomes and cost-effectiveness before extending coverage and adequate reimbursement to such new technologies. In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or the Medicare Modernization Act, changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly under a new Part D and introduced a new reimbursement methodology based on average sale prices for physician-administered drugs. In addition, this legislation provided authority for limiting the number of drugs that will be covered in any therapeutic class. Cost-reduction initiatives and other provisions of this legislation could decrease the coverage and reimbursement that we receive for any approved products. While the Medicare Modernization Act applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the Medicare Modernization Act may result in a similar reduction in payments from private payors. In light of such challenges to prices and increasing levels of evidence of the benefits and clinical outcomes of new technologies, we cannot be sure that coverage will be available for any product candidate that we commercialize, and, if available, that the reimbursement rates will be adequate. If we are unable to obtain adequate levels of coverage and reimbursement for our product candidates, our ability to generate revenue will be compromised.

Our potential customers, including hospitals, physicians and other healthcare providers that purchase certain injectable drugs administered during a procedure, such as our product candidates, generally rely on third-party payors to pay for all or part of the costs and fees associated with the drug and the procedures administering the drug. These third-party payors may pay separately for the drug or may bundle or otherwise include the costs of the drug in the payment for the procedure. We are unable to predict at this time whether our product candidates, if approved, will be eligible for such separate payments. To the extent there is no separate payment for our product candidates, there may be further uncertainty as to the adequacy of reimbursement amounts. Nor can we predict at this time the adequacy of payments, whether made separately for the drug and procedure or with a bundled or otherwise aggregate payment amount for the drug and procedure. In addition, obtaining and maintaining adequate coverage and reimbursement status is time consuming and costly.

Because each third-party payor individually approves coverage and reimbursement levels, obtaining coverage and adequate reimbursement is a time consuming, costly and sometimes unpredictable process. We may be required to provide scientific and clinical support, medical necessity or both for the use of any product to each third-party payor separately with no assurance that approval would be obtained, and we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost-effectiveness, medical necessity or both of our products. This process could delay

the market acceptance of any product and could have a negative effect on our future revenues and operating results.

Third-party payors may deny coverage and reimbursement status altogether of a given drug product, or cover the product, but may also establish prices at levels that are too low to enable us to realize an appropriate return on our investment in product development. Because the rules and regulations regarding coverage and reimbursement change frequently, in some cases on short notice, even when there is favorable coverage and reimbursement, future changes may occur that adversely impact such favorable coverage and reimbursement status. Further, the net reimbursement for drug products may be subject to additional reductions if there are changes to laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States.

The unavailability or inadequacy of third-party coverage and reimbursement could negatively affect the market acceptance of our product candidates and the future revenues we may expect to receive from those products. In addition, we are unable to predict what additional legislation or regulation relating to the healthcare industry or third-party coverage and reimbursement may be enacted in the future, or what effect such legislation or regulation would have on our business.

Our products may not gain market acceptance, in which case we may not be able to generate product revenues.

Even if the FDA, EMA or any comparable foreign regulatory agency approves the marketing of any product candidates that we develop, physicians, healthcare providers, patients or the medical community may not accept or use them. Efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may not be successful. If COR-003, COR-004, COR-005 or any other product candidate that we develop does not achieve an adequate level of acceptance, we may not generate significant product revenues or any profits from operations. The degree of market acceptance of COR-003, COR-004, COR-005 or any of our product candidates that are approved for commercial sale will depend on a variety of factors, including, but not limited to:

- whether clinicians and potential patients perceive our product candidates to have better efficacy, safety and tolerability profile, and ease of use compared with our competitors;
- the timing of market introduction;
- the number of competing products;
- our ability to provide acceptable evidence of safety and efficacy;
- the prevalence and severity of any side effects;
- relative convenience and ease of administration;
- cost-effectiveness;
- patient diagnostics and screening infrastructure in each market;
- marketing and distribution support; and
- availability of coverage, reimbursement and adequate payment from health maintenance organizations and other third-party payors, both public and private.

In addition, the potential market opportunity for COR-003, COR-004, COR-005 or any other product candidate we may develop is difficult to estimate precisely. Our estimates of the potential market opportunity are predicated on several key assumptions such as industry knowledge and publications, third-party research reports and other surveys. While we believe that our internal assumptions are reasonable, these assumptions may be inaccurate. If any of the assumptions proves to

be inaccurate, then the actual market for COR-003 or our other product candidates could be smaller than our estimates of the potential market opportunity. If the actual market for COR-003 or our other product candidates is smaller than we expect, or if the products fail to achieve an adequate level of acceptance by physicians, health care payors and patients, our product revenue may be limited and we may be unable to achieve or maintain profitability. Further, given the limited number of treating physicians, if we are unable to convince a significant number of such physicians of the value of our product candidates, we may be unable to achieve a sufficient market share to make our products, if approved, profitable.

Risks Related to Our Reliance on Third Parties

We rely on third parties to conduct our nonclinical and clinical trials and if these third parties perform in an unsatisfactory manner, our business could be substantially harmed.

We have relied upon and plan to continue to rely upon third-party CROs to conduct and monitor and manage data for our ongoing nonclinical and clinical programs, and may not currently have all of the necessary contractual relationships in place to do so. Once we have established contractual relationships with such third-party CROs, we will have only limited control over their actual performance of these activities. Nevertheless, we are responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol, legal, regulatory, environmental and scientific standards and our reliance on the CROs does not relieve us of our regulatory responsibilities.

We and our CROs and other vendors are required to comply with current Good Manufacturing Practices, or cGMP, current Good Clinical Practices, or cGCP, and Good Laboratory Practice, or GLP, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the European Union and any comparable foreign regulatory agency for all of our product candidates in nonclinical and clinical development. Regulatory authorities enforce these regulations through periodic inspections of study sponsors, principal investigators, trial sites and other contractors. If we or any of our CROs or vendors fail to comply with applicable regulations, the data generated in our nonclinical and clinical trials may be deemed unreliable and the FDA, EMA or any comparable foreign regulatory agency may require us to perform additional nonclinical and clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that all of our clinical trials comply with cGCP regulations. In addition, our clinical trials must be conducted with products produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

Our business involves the controlled use of hazardous materials, chemicals, biologicals and radioactive compounds. Substantially all such use is outsourced to third-party CRO manufacturers and clinical sites. Although we believe that our third-party CROs safety procedures for handling and disposing of such materials comply with industry standards, there will always be a risk of accidental contamination or injury. By law, radioactive materials may only be disposed of at certain approved facilities. If liable for an accident, or if it suffers an extended facility shutdown, we or our CROs could incur significant costs, damages or penalties.

Our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our ongoing nonclinical and clinical programs. If our CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. Our CROs may also generate higher costs than anticipated. As a result, our results

of operations and the commercial prospects for our product candidates would be harmed, our costs could increase, and our ability to generate revenue could be delayed.

If any of our relationships with these third-party CROs terminates, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. If we are able to replace a CRO, switching or adding additional CROs involves additional cost and requires management time and focus and there is a natural transition period when a new CRO commences work. As a result, delays could occur, which could hurt our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future.

The failure of our suppliers to supply us with the agreed upon drug substance or drug product could hurt our business.

We do not currently, and do not expect to in the future, independently conduct manufacturing activities for our product candidates. We expect to rely on third-party suppliers for the drug substance and drug product for our product candidates. The failure of these suppliers to perform as contracted, or the need to identify new suppliers, could result in a delay in the development of our product candidates. A delay in the development of our product candidates or having to enter into a new agreement with a different third party on less favorable terms than we have with our current suppliers could hurt our business.

We and our collaborators and contract manufacturers are subject to significant regulation with respect to manufacturing our product candidates. The manufacturing facilities on which we rely may not continue to meet regulatory requirements or may not be able to meet supply demands.

All entities involved in the preparation of therapeutics for clinical trials or commercial sale, including our existing contract manufacturers for our product candidates, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in late-stage clinical trials must be manufactured in accordance with cGMP. These regulations govern manufacturing processes and procedures, including record keeping, and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of contaminants or to inadvertent changes in the properties or stability of our product candidates that may not be detectable in final product testing. We, our collaborators or our contract manufacturers must supply all necessary documentation in support of an NDA or foreign equivalent on a timely basis and must adhere to GLP and cGMP regulations enforced by the FDA and other regulatory agencies through their facilities inspection program. Some of our contract manufacturers have never produced a commercially approved pharmaceutical product and therefore have not obtained the requisite regulatory authority approvals to do so. The facilities and quality systems of some or all of our collaborators and third-party contractors must pass a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of our product candidates or any of our other potential products. In addition, the regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the preparation of our product candidates or our other potential products or the associated quality systems for compliance with the regulations applicable to the activities being conducted. Although we oversee the contract manufacturers, we cannot control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with the regulatory requirements. If these facilities do not pass a pre-approval plant inspection, regulatory approval of the products may not be granted or may be substantially delayed until any violations are corrected to the satisfaction of the regulatory authority, if ever.

The regulatory authorities also may, at any time following approval of a product for sale, audit the manufacturing facilities of our collaborators and third-party contractors. If any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of our product specifications or applicable regulations occurs independent of such an inspection or audit, we or the relevant regulatory authority may require remedial measures that may be costly and/or time consuming for us or a third party to implement, and that may include the temporary or permanent suspension of a clinical trial or commercial sales or the temporary or permanent closure of a facility.

If we, our collaborators or any of our third-party manufacturers fail to maintain regulatory compliance, the FDA or another applicable regulatory authority could impose regulatory sanctions including, among other things, refusal to approve a pending application our product candidates, withdrawal of an approval or suspension of production.

Additionally, if the supply from one approved manufacturer is interrupted, an alternative manufacturer would need to be qualified through an NDA supplement or equivalent foreign regulatory filing, which could result in further delay. The regulatory agencies may also require additional studies if a new manufacturer is relied upon for commercial production. Switching manufacturers may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines.

These factors could cause us to incur higher costs and could cause the delay or termination of clinical trials, regulatory submissions, required approvals or commercialization of our product candidates. Furthermore, if our suppliers fail to meet contractual requirements and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, our clinical trials may be delayed or we could lose potential revenue.

Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Because we rely on third parties to develop and manufacture our product candidates, we must, at times, share trade secrets with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with our collaborators, advisors, employees, and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, such as trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may harm our business.

Risks Related to Our Intellectual Property

If we or our licensors are unable to obtain and maintain effective patent rights for our technologies, product candidates or any future product candidates, or if the scope of the patent rights obtained is not sufficiently broad, we may not be able to compete effectively in our markets.

In addition to the exclusivity provided for our product candidates with regulatory orphan drug status, we rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our technologies and product candidates. Our success depends in large part on our and our licensors' ability to obtain and maintain patent and other intellectual property protection in the United States and in other countries with respect to our proprietary technology and product candidates.

We have sought to protect our proprietary position by filing patent applications in the United States and abroad related to our novel technologies and products that are important to our business. This process is expensive and time consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost, in a timely manner or in all jurisdictions. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, in some circumstances, we do not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from third parties. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain and involves complex legal and factual questions for which legal principles remain unsolved. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our product candidates in the United States or in foreign countries. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions remain confidential for a period of time after filing, and some remain so until issued. Therefore, we cannot be certain that we were the first to file any patent application related to our product candidates, or whether we were the first to make the inventions claimed in our owned patents or pending patent applications, nor can we know whether those from whom we license patents were the first to make the inventions claimed or were the first to file. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. There is no assurance that all potentially relevant prior art relating to our patents and patent applications has been found, which can invalidate a patent or prevent a patent from issuing from a pending patent application. Even if patents do successfully issue, and even if such patents cover our product candidates, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed, found unenforceable or invalidated, which could allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property, provide exclusivity for our product candidates, prevent others from designing around our claims or provide us with a competitive advantage. Any of these outcomes could impair our ability to prevent competition from third parties.

We and/or our licensors have filed several patent applications covering various aspects of our product candidates. We cannot offer any assurances about which, if any, patents will issue, the breadth of any such patent, or whether any issued patents will be found invalid and unenforceable or will be challenged by third parties. Any successful opposition to these patents or any other patents owned by or licensed to us after patent issuance could deprive us of rights necessary for the successful commercialization of any product candidates that we may develop. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate under patent protection could be reduced.

We may not have sufficient patent terms to effectively protect our products and business.

Patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is first filed. Although various extensions may be available, the life of a patent, and the protection it affords, is limited. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such product candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours or otherwise provide us with a

competitive advantage. Even if patents covering our product candidates are obtained, once the patent life has expired for a product, we may be open to competition from generic medications.

While patent term extensions in the United States and under supplementary protection certificates in the European Union may be available to extend the patent exclusivity term for our product candidates, we cannot provide any assurances that any such patent term extension will be obtained and, if so, for how long.

Patent policy and rule changes could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. The laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Assuming the other requirements for patentability are met, in the United States prior to March 15, 2013, the first to invent the claimed invention is entitled to the patent, while outside the United States, the first to file a patent application is entitled to the patent. After March 15, 2013, under the Leahy-Smith America Invents Act, or the AIA, enacted on September 16, 2011, the United States has moved to a first inventor to file system. The AIA also includes a number of significant changes that affect the way patent applications will be prosecuted and may also affect patent litigation. The effects of these changes are currently unclear as the United States Patent and Trademark Office, or the USPTO, is still implementing various regulations, the courts have yet to address many of these provisions and the applicability of the act and new regulations on specific patents discussed herein have not been determined and would need to be reviewed. In general, the AIA and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. In addition, recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on future actions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

Third-party claims of intellectual property infringement may expose us to substantial liability or prevent or delay our development and commercialization efforts.

Our commercial success depends in part on our ability to develop, manufacture, market and sell our product candidates, if approved, and use our proprietary technology without alleged or actual infringement, misappropriation or other violation of the patents and proprietary rights of third parties. There have been many lawsuits and other proceedings involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions and reexamination proceedings before the USPTO, and corresponding foreign patent offices. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing product candidates. Some claimants may have substantially greater resources than we do and may be able to sustain the costs of complex intellectual property litigation to a greater degree and for longer periods of time than we could. In addition, patent holding companies that focus solely on extracting royalties and settlements by enforcing patent rights may target us. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the intellectual property rights of third parties.

Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to compositions, formulations, methods of manufacture or methods of treatment related to the use or manufacture of our product candidates. We cannot be sure that we know of each and every patent and pending application in the United States and abroad that is relevant or necessary to the commercialization of our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents upon which our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our product candidates, any compositions formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtained a license under the applicable patents, or until such patents expire or are finally determined to be invalid or unenforceable. Similarly, if any third-party patents were held by a court of competent jurisdiction to cover aspects of our compositions, formulations, or methods of treatment, prevention or use, the holders of any such patents may be able to block our ability to develop and commercialize the applicable product candidate unless we obtained a license or until such patent expires or is finally determined to be invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms, or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates, if approved. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure.

Additional competitors could enter the market with generic versions of our products, which may result in a decline in sales of affected products.

Under the Hatch-Waxman Act, a pharmaceutical manufacturer may file an abbreviated new drug application, or ANDA, seeking approval of a generic copy of an approved innovator product. Under the Hatch-Waxman Act, a manufacturer may also submit an NDA under section 505(b)(2) that references the FDA's prior approval of the innovator product. A 505(b)(2) NDA product may be for a new or improved version of the original innovator product. Hatch-Waxman also provides for certain periods of regulatory exclusivity, which preclude FDA approval, or, in some circumstances, FDA filing and reviewing, of an ANDA or 505(b)(2) NDA. These include, subject to certain exceptions, the period during which an FDA-approved drug is subject to orphan drug exclusivity. Although COR-003 is being developed as a new chemical entity, or NCE, we intend to rely on orphan drug exclusivity rather than NCE exclusivity for nonpatent protection of COR-003. In addition to the benefits of regulatory exclusivity, an innovator NDA holder may have patents claiming the active ingredient, product formulation or an approved use of the drug, which would be listed with the product in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations," known as the "Orange Book." If there are patents listed in the Orange Book, a generic or 505(b)(2) applicant that seeks to market its product before expiration of the patents must include in the ANDA what is known as a "Paragraph IV certification," challenging the validity or enforceability of, or claiming non-infringement of, the listed patent or patents. Notice of the certification must be given to the innovator, too, and if within 45 days of receiving notice the innovator sues to protect its patents, approval of the ANDA is stayed for 30 months, or as lengthened or shortened by the court.

Accordingly, if COR-003 or any of our other product candidate is approved, competitors could file ANDAs for generic versions of our product candidates, or 505(b)(2) NDAs that reference our product candidates, respectively. If there are patents listed for our product candidates in the Orange Book, those ANDAs and 505(b)(2) NDAs would be required to include a certification as to each listed patent indicating whether the ANDA applicant does or does not intend to challenge the patent. We cannot predict whether any patents issuing from our pending patent applications will be eligible for listing in the Orange Book, how any generic competitor would address such patents, whether we would sue on any such patents or the outcome of any such suit.

We may not be successful in securing or maintaining proprietary patent protection for products and technologies we develop or license. Moreover, if any patents that are granted and listed in the Orange Book are successfully challenged by way of a Paragraph IV certification and subsequent litigation, the affected product could immediately face generic competition and its sales would likely decline rapidly and materially. Should sales decline, we may have to write off a portion or all of the intangible assets associated with the affected product and our ability to generate revenue could be compromised.

Although we are not currently involved in any litigation, we may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time consuming and unsuccessful.

Competitors may infringe upon our patents or the patents of our licensors. Although we are not currently involved in any litigation, if we or one of our licensing partners were to initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that the patent covering our product candidate is invalid and/or unenforceable, or request declaratory judgment that there is no infringement. In patent litigation in the United States, defendant counterclaims alleging invalidity, noninfringement and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, nonobviousness or non-lack of enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld material relevant information from the USPTO, or made a misleading statement, during prosecution. The outcome following legal assertions of invalidity and unenforceability is unpredictable.

Interference or derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms, or at all. Our defense of litigation or interference proceedings may fail and, even if successful, may result in substantial costs, and distract our management and other employees. In addition, the uncertainties associated with litigation could compromise our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties or enter into development partnerships that would help us bring our product candidates to market, if approved.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could hurt the market price of our ordinary shares.

We have not yet registered a trademark and failure to secure or maintain adequate protection for our trademarks could adversely affect our business.

We have filed a U.S., Canadian and International (Madrid Protocol) trademark application designating Australia, China, European Community, India, Israel, Japan, Mexico and Turkey for the mark, “Strongbridge Biopharma.” If the U.S. or any foreign trademark offices raise any objections, we may be unable to overcome such objections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Oppositions or cancellation proceedings have been filed and may in the future be filed against our trademarks, and our trademarks may not survive such proceedings.

Furthermore, third parties may allege in the future, that a trademark or trade name that we elect to use for our product candidates may cause confusion in the marketplace. We evaluate such potential allegations in the course of our business, and such evaluations may cause us to change our commercialization or branding strategy for our product candidates, which may require us to incur additional costs. Moreover, any name we propose to use with our product candidate in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA.

At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, domain names or copyrights may be ineffective and could result in substantial costs and diversion of resources.

In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks alleging that the use of a corporate name or logo, product names or other signs by which we distinguish our products and services are infringing their trademark rights. The outcome of such claims is uncertain and may adversely affect our freedom to use our corporate name or other relevant signs. If litigation arises in this area, it may lead to significant costs and diversion of management and employee attention.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties or that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

We may employ individuals who were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and independent contractors do not use the proprietary information or know-how of others in their work for us, and we are not currently subject to any claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties, we may in the future be subject to such claims. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

We may be subject to claims challenging the inventorship of our patents and other intellectual property.

Although we are not currently experiencing any claims challenging the inventorship of our patents or ownership of our intellectual property, we may in the future be subject to claims that former employees, collaborators or other third parties have an interest in our patents or other intellectual property as an inventor or co-inventor. For example, we may have inventorship disputes arise from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Further, licensing partners may not prosecute patents in certain jurisdictions in which we may obtain commercial rights, thereby precluding the possibility of later obtaining patent protection in these countries. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and may also export infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Risks Related to Government and Regulation

Even if one or more of our product candidates obtains regulatory approval, we will be subject to ongoing obligations and continued regulatory requirements, which may result in significant additional expense.

If regulatory approval is obtained for any of our product candidates, the product will remain subject to continual regulatory review. Any regulatory approvals that we receive for our product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing

testing, including Phase 4 clinical trials and surveillance to monitor the safety and efficacy of the product candidate. In addition, if the FDA, the EMA or any comparable foreign regulatory authority approves any of our product candidates, we will be subject to ongoing regulatory obligations and oversight by regulatory authorities, including with respect to the manufacturing processes, labeling, packing, distribution, adverse event reporting, storage, advertising and marketing restrictions, and recordkeeping and, potentially, other post-marketing obligations, all of which may result in significant expense and limit our ability to commercialize such products. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs and cGCPs for any clinical trials that we conduct post-regulatory approval. Because our Phase 3 clinical trial of COR-003 will collect safety data for only 90 patients, we currently expect that we would be required by the FDA and the EMA to collect additional safety data post-approval.

In addition, approved products, manufacturers and manufacturers' facilities are subject to continual review and periodic inspections. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the product;
- withdrawal of the product from the market, or voluntary or mandatory product recalls;
- fines, disgorgement of profits or revenues, warning letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us;
- suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products; and
- injunctions or the imposition of civil or criminal penalties.

If any of these events occurs, our ability to sell such product may be impaired, and we may incur substantial additional expense to comply with regulatory requirements. The policies of the FDA, the EMA or any comparable foreign regulatory agency may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any regulatory approval that we may have obtained, which would compromise our ability to achieve or sustain profitability.

If we obtain orphan drug designation for our product candidates from the FDA and/or the EMA, orphan drug designation may not ensure that we will enjoy market exclusivity in a particular market, and if we fail to obtain or maintain orphan drug exclusivity for our product candidates, we may be subject to earlier competition and our potential revenue will be reduced.

Under the Orphan Drug Act of 1983, the FDA may designate a product as an orphan drug if it is intended to treat an orphan disease or condition, defined as a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the European Union, the EMA's Committee for Orphan Medicinal Products grants orphan drug designation to promote the development of products that are intended for the diagnosis, prevention, or treatment of a life-threatening or chronically debilitating condition affecting not more than 5 in 10,000 persons in the European Union. Additionally, designation is granted for

products intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition when, without incentives, it is unlikely that sales of the drug in the European Union would be sufficient to justify the necessary investment in developing the drug or biological product or where there is no satisfactory method of diagnosis, prevention or treatment, or, if such a method exists, the medicine must be of significant benefit to those affected by the condition.

In the United States, orphan drug designation entitles a party to financial incentives, such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. In addition, if a product receives the first FDA approval for the indication for which it has orphan drug designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other application to market the same drug for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity or where the manufacturer is unable to assure sufficient product quantity. In the European Union, orphan drug designation entitles a party to financial incentives such as a reduction of fees or fee waivers and ten years of market exclusivity following drug or biological product approval. This period may be reduced to six years if the orphan drug designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity.

COR-003 has been granted orphan drug designation for the treatment of endogenous Cushing's syndrome in the United States and Europe. COR-005 has been granted orphan drug designation for the treatment of acromegaly in the United States and the European Union. Even if we obtain orphan drug designation for our other product candidates, we may not be the first to obtain regulatory approval for any particular orphan indication due to the uncertainties associated with developing biopharmaceutical products. Further, even if we obtain orphan drug designation for a product candidate, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties can be approved for the same condition. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process.

Enacted and future legislation may increase the difficulty and cost for us to obtain regulatory approval of and commercialize our product candidates, and may affect the prices we may set.

In the United States and the European Union, there have been a number of legislative, regulatory and proposed changes regarding the healthcare system. These changes could prevent or delay regulatory approval of our product candidates, restrict or regulate post-approval activities, and affect our ability to sell profitably any products for which we obtain regulatory approval and begin to commercialize.

As a result of legislative proposals and the trend toward managed health care in the United States, third-party payors are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement of new drugs. In the United States, the Medicare Modernization Act changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly under a new Part D and introduced a new reimbursement methodology based on average sale prices for physician-administered drugs. In addition, this legislation provided authority for limiting the number of drugs that will be covered in any therapeutic class. Cost-reduction initiatives and other provisions of this legislation could decrease the coverage and reimbursement that we receive for any approved products. While the Medicare Modernization Act applies only to drug benefits for Medicare beneficiaries, private payors often follow the Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the Medicare Modernization Act may result in a similar reduction in payments from private payors.

In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, PPACA, a sweeping law intended, among other things, to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for health care and health insurance industries, impose new taxes and fees on the health industry, and impose additional health policy reforms. PPACA, among other things: increased the statutory minimum Medicaid rebates a manufacturer must pay under the Medicaid Drug Rebate Program; addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected; and established a new Medicare Part D coverage gap discount program in which manufacturers must provide 50% point-of-sale discounts on negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period as a condition for the manufacturer's outpatient drugs to be covered under Part D and implemented payment system reforms, including a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models. Further, the PPACA imposed a significant annual nondeductible fee on entities that manufacture or import specified branded prescription drug products and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs. We expect that additional healthcare reform measures will likely be adopted in the future, any of which may increase our regulatory burdens and operating costs and limit the amounts that federal, state and foreign governments will reimburse for healthcare products and services, which could result in reduced demand for our products, if approved, or additional pricing pressures.

Moreover, other legislative changes have also been proposed and adopted in the United States since PPACA was enacted. On August 2, 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021 was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect on April 1, 2013 and will stay in effect through 2024 unless additional Congressional action is taken. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other health care funding, which could compromise the ability of patients and third-party payors to purchase our product candidates.

In the European Union, proposed new clinical trial regulations will centralize clinical trial approval, which eliminates redundancy, but in some cases this may extend timelines for clinical trial approvals due to potentially longer wait times. Proposals to require specific consents for use of data in research, among other measures, may increase the costs and timelines for our product development efforts. Austerity measures in certain European nations may also affect the prices we are able to seek if our products are approved, as discussed below.

Both in the United States and in the European Union, legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We do not know whether additional legislative changes will be enacted, whether the regulations, guidance or interpretations will be changed, or what the impact of such changes on the regulatory approvals of our product candidates, if any, may be.

Our relationships with customers, consultants and payors will be subject to applicable fraud and abuse, privacy and security, transparency and other healthcare laws and regulations, which, if violated, could expose us to criminal sanctions, civil penalties, exclusion from government healthcare programs, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and others play a primary role in the recommendation and prescription of any products for which we may in the future obtain regulatory approval and commercialize. Our current and future arrangements with third-party payors, consultants, customers, physicians and others may expose us to broadly applicable fraud and abuse and other healthcare federal and state laws and regulations, including in the United States, that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our products for which we obtain regulatory approval. Potentially applicable healthcare laws and regulations include, but are not limited to, the following:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or paying remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for, purchasing, leasing, ordering, arranging for, or recommending the purchase, lease, or order of, any good, facility, item or service for which payment may be made under U.S. government healthcare programs such as Medicare and Medicaid;
- the federal civil and criminal false claims laws and civil monetary penalties laws, including civil whistleblower or qui tam actions, which prohibit, among other things, any person or entity from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment or approval to the federal government or knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government, or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay or transmit money or property to the federal government;
- though we are not currently regulated under the Privacy Rule or the Security Rule of the Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, which impose various obligations with respect to safeguarding the privacy, security and transmission of individually identifiable health information, it may implicate certain aspects of our business relationships;
- the health care fraud provisions of HIPAA, which impose criminal liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, or to obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of, or payment for, healthcare benefits, items or services;
- the federal Physician Payments Sunshine Act under PPACA and its implementing regulations, which requires certain manufacturers of drugs, devices, biologics and medical supplies to annually report to the Centers for Medicare & Medicaid Services information related to payments and other transfers of value made by such manufacturers to physicians and teaching hospitals, and ownership and investment interests held by physicians or their immediate family members; and
- analogous laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements, research, distribution and claims involving

healthcare items or services reimbursed by state governmental and non-governmental third-party payors, including private insurers, state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, and state requirements for manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures and other restrictions on drug manufacturer marketing practices.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available under the U.S. federal Anti-Kickback Statute and analogous state laws, it is possible that some of our current and future business activities could be subject to challenge under one or more of such laws. In addition, recent health care reform legislation has strengthened these laws. For example, PPACA, among other things, amends the intent requirement of the U.S. federal Anti-Kickback Statute and criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of these statutes or specific intent to violate them in order to be in violation. Moreover, PPACA provides that the government may assert that a claim including items or services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations, agency guidance or case law involving applicable healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to, without limitation, significant civil, criminal and administrative penalties, damages, fines, exclusion from U.S. government funded healthcare programs, such as Medicare and Medicaid, imprisonment, disgorgement, enhanced government reporting and oversight, contractual damages, reputational harm, diminished profits and future earnings and/or the curtailment or restructuring of our operations. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses or divert our management's attention from the operations of our business. If any of the physicians or other providers or entities with whom we expect to do business are found to be not in compliance with applicable laws, they may be subject to similar penalties, including, without limitation, criminal, civil or administrative sanctions, including exclusions from government-funded healthcare programs.

We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws and anti-money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We can face criminal liability and other serious consequences for violations which can harm our business.

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls, the U.S. Foreign Corrupt Practices Act of 1977, as amended, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors and other partners from authorizing, promising, offering, or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties for clinical trials outside of the United States, to sell our products abroad once we enter a commercialization phase and/or to obtain necessary permits, licenses, patent registrations and other regulatory approvals. We have direct or indirect interactions with officials and employees of

government agencies or government-affiliated hospitals, universities and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors and other partners, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences.

Risks Related to the Offering and Our Ordinary Shares

The price of our ordinary shares is likely to be volatile and may fluctuate due to factors beyond our control.

The market price of our ordinary shares is likely to be highly volatile and subject to wide fluctuations in response to a variety of factors, many of which are beyond our control, including:

- positive or negative results of testing and clinical trials by us, strategic partners or competitors;
- delays in in-licensing or acquiring additional complementary product candidates;
- any delay in the commencement, enrollment and the ultimate completion of clinical trials;
- technological innovations or commercial product introductions by us or competitors;
- failure to successfully develop and commercialize any of our product candidates, if approved;
- changes in government regulations;
- developments concerning proprietary rights, including patents and litigation matters;
- public concern relating to the commercial value or safety of any of our product candidates;
- financing or other corporate transactions, or inability to obtain additional funding;
- failure to meet or exceed expectations of the investment community;
- announcements of significant licenses, acquisitions, strategic partnerships or joint ventures by us or our competitors;
- publication of research reports or comments by securities or industry analysts; or
- general market conditions in the pharmaceutical industry or in the economy as a whole.

The share price of publicly traded emerging biopharmaceutical and drug discovery and development companies has been highly volatile and is likely to remain highly volatile in the future. In addition, the stock market in general has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of individual companies. Broad market and industry factors may hurt the market price of companies' stock, including ours, regardless of actual operating performance. The market price of our ordinary shares may decline below the initial public offering price in this offering, and investors may lose some or all of their investment. Shares of our stock have been quoted on the Norwegian over-the-counter market. Continued quotation in this market could contribute to volatility in our share price.

An active market in our ordinary shares may not develop or be liquid enough for investors to resell our ordinary shares.

We cannot predict the extent to which an active market for our ordinary shares will develop or be sustained after this offering, or how the development of such a market might affect the market price for our ordinary shares. The public offering price of our ordinary shares in this offering has been determined by negotiations between us and the underwriters based on a number of factors, including

market conditions in effect at the time of this offering, and may not be indicative of the price at which our ordinary shares will trade following completion of this offering. Investors may not be able to sell their ordinary shares at or above the initial public offering price in this offering.

If certain existing investors participate in this offering, the available public float for our ordinary shares could be reduced and the liquidity of our ordinary shares could be adversely affected.

Certain of our existing shareholders who beneficially own more than 5% of our ordinary shares and their affiliates have indicated an interest in purchasing up to an aggregate of \$20.0 million of our ordinary shares in this offering at the initial public offering price per share. Based on the initial public offering price of \$10.00 per share, these entities would purchase up to an aggregate of 2,000,000 of the 2,500,000 shares in this offering, based on these indications of interest. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters may determine to sell more, less or no shares in this offering to any of these entities, or any of these entities may determine to purchase more, less or no shares in this offering.

Any shares purchased by existing shareholders could reduce the available public float for our ordinary shares. As a result, any purchase of ordinary shares by such entities in this offering may reduce the liquidity of our ordinary shares relative to what it would have been had these shares been purchased by other investors.

Future sales, or the possibility of future sales, of a substantial number of our ordinary shares could adversely affect the price of our ordinary shares.

Future sales of a substantial number of our ordinary shares, or the perception that such sales will occur, could cause a decline in the market price of our ordinary shares. Following the completion of this offering, we will have 21,205,382 ordinary shares outstanding, assuming the underwriters do not exercise their option to purchase additional ordinary shares, based on 18,705,382 ordinary shares outstanding as of October 14, 2015. This includes the ordinary shares in this offering, which may be resold in the public market immediately without restriction, unless purchased by our affiliates. Approximately 88% of the ordinary shares outstanding are expected to be held by existing shareholders. A significant portion of these ordinary shares will be subject to the lock-up agreements described in the “Underwriting” section of this prospectus. If, after the end of such lock-up agreements, these shareholders sell substantial amounts of ordinary shares in the public market, or the market perceives that such sales may occur, the market price of our ordinary shares and our ability to raise capital through an issue of equity securities in the future could be adversely affected. We also intend to enter into a registration rights agreement upon consummation of this offering pursuant to which we will agree under certain circumstances to file a registration statement to register the resale of the ordinary shares held by certain of our existing shareholders, as well as to cooperate in certain public offerings of such ordinary shares. In addition, following the completion of this offering, we intend to adopt a new omnibus equity incentive plan under which we would have the discretion to grant a broad range of equity-based awards to eligible participants. We intend to register all ordinary shares that we may issue under this equity compensation plan. Once we register these ordinary shares, they can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates and the lock-up agreements described in the “Underwriting” section of this prospectus. If a large number of our ordinary shares or securities convertible into our ordinary shares are sold in the public market after they become eligible for sale, the sales could reduce the trading price of our ordinary shares and impede our ability to raise future capital.

We expect to be classified a passive foreign investment company for U.S. federal income tax purposes, which could result in adverse U.S. federal income tax consequences to U.S. Holders of our ordinary shares.

A non-U.S. corporation generally will be classified as a passive foreign investment company, or PFIC, for U.S. federal income tax purposes for any taxable year if either (1) 75% or more of its gross income for such year consists of certain types of “passive” income or (2) 50% or more of the value of its assets (determined on the basis of a quarterly average) during such year produce or are held for the production of passive income. For this purpose, “passive income” generally includes, among other items of income, dividends, interest, royalties, rents and gains from commodities and securities transactions and from the sale or exchange of property that gives rise to passive income, and a non-U.S. corporation is treated as owning a proportionate share of the assets and earning a proportionate share of the income of any other corporation in which such non-U.S. corporation owns, directly or indirectly, more than 25% of the value of such other corporation’s stock. Based on our projected income, assets and activities, we expect that we will be treated as a PFIC for the current taxable year and for the foreseeable future. Accordingly, a U.S. Holder, as defined under the section “Taxation—Material U.S. Federal Income Tax Considerations for U.S. Holders,” would be subject to substantially increased U.S. federal income tax liability, including upon the receipt of any “excess distributions” from us and upon the sale or other disposition of our ordinary shares. Although certain elections may be available to mitigate the adverse impact of the PFIC rules, such elections may result in a current U.S. federal tax liability prior to any distribution on or disposition of our ordinary shares. Further, there can be no assurances that we will supply U.S. Holders with information that such U.S. Holders are required to report under the rules governing such elections. Accordingly, the acquisition of our ordinary shares may not be an appropriate investment for certain holders that are not tax-exempt organizations. U.S. Holders should consult their tax advisers regarding the application of the PFIC rules to an investment in our ordinary shares.

If securities or industry analysts do not publish research, or publish inaccurate or unfavorable research, about our business, the price of our ordinary shares and our trading volume could decline.

The trading market for our ordinary shares will depend in part on the research and reports that securities or industry analysts publish about us or our business. If no or too few securities or industry analysts commence coverage of our company, the trading price for our ordinary shares would likely be negatively affected. In the event securities or industry analysts initiate coverage, if one or more of the analysts who cover us downgrade our ordinary shares or publish inaccurate or unfavorable research about our business, the price of our ordinary shares would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our ordinary shares could decrease, which might cause the price of our ordinary shares and trading volume to decline.

If you purchase ordinary shares in this offering, you will suffer immediate dilution of your investment.

The initial public offering price of our ordinary shares is substantially higher than the as adjusted net tangible book value per ordinary share. Therefore, if you purchase ordinary shares in this offering, you will pay a price per ordinary share that substantially exceeds our as adjusted net tangible book value per ordinary share after this offering. To the extent outstanding options are exercised, you will incur further dilution. Based on the initial public offering price of \$10.00 per ordinary share, you will experience immediate dilution of \$7.06 per ordinary share, representing the difference between our as adjusted net tangible book value per ordinary share after giving effect to this offering and the initial public offering price. In addition, purchasers of ordinary shares in this offering will have contributed approximately 18% of the aggregate price paid by all purchasers of our ordinary shares but will own only approximately 12% of our ordinary shares outstanding after this offering. See “Dilution.”

We have broad discretion in the use of the net proceeds from this offering and may not use them effectively.

Our management will have broad discretion in the application of the net proceeds from this offering and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our ordinary shares. The failure by our management to apply these funds effectively could result in financial losses, cause the market price of our ordinary shares to decline and delay the development of our product candidates. Pending their use, we may invest the net proceeds from this offering in a manner that does not produce income or that loses value.

We have never paid cash dividends, do not expect to pay dividends in the foreseeable future and our ability to pay dividends, or repurchase or redeem our ordinary shares, is limited by law.

We have not paid any dividends since our inception and do not anticipate paying any dividends on our ordinary shares in the foreseeable future. Even if future operations lead to significant levels of distributable profits, we currently intend that any earnings will be reinvested in our business and that dividends will not be paid until we have an established revenue stream to support continuing dividends. The proposal to pay future dividends to shareholders will in addition effectively be at the sole discretion of our board of directors after taking into account various factors our board of directors deems relevant, including our business prospects, capital requirements, financial performance and new product development. In addition, payment of future dividends is subject to certain limitations under the Irish Companies Act 2014, or the Irish Companies Act. The Irish Companies Act, among other requirements, require Irish companies to have distributable reserves available for distribution equal to or greater than the amount of the proposed dividend. See “Description of Share Capital and Articles of Association.” Accordingly, investors cannot rely on dividend income from our ordinary shares and any returns on an investment in our ordinary shares will likely depend entirely upon any future appreciation in the price of our ordinary shares.

We will be a foreign private issuer and, as a result, we will not be subject to U.S. proxy rules and will be subject to Exchange Act reporting obligations that, to some extent, are more lenient and less frequent than those of a U.S. domestic public company.

Upon consummation of this offering, we will report under the Securities Exchange Act of 1934, as amended, or the Exchange Act, as a non-U.S. company with foreign private issuer status. Because we qualify as a foreign private issuer under the Exchange Act and although we are subject to Irish laws and regulations with regard to such matters and intend to furnish quarterly financial information to the Securities and Exchange Commission, we are exempt from certain provisions of the Exchange Act that are applicable to U.S. domestic public companies, including: (1) the sections of the Exchange Act regulating the solicitation of proxies, consents or authorizations with respect to a security registered under the Exchange Act; (2) the sections of the Exchange Act requiring insiders to file public reports of their stock ownership and trading activities and liability for insiders who profit from trades made in a short period of time; and (3) the rules under the Exchange Act requiring the filing with the SEC of quarterly reports on Form 10-Q containing unaudited financial and other specified information, or current reports on Form 8-K upon the occurrence of specified significant events. In addition, foreign private issuers are not required to file their annual report on Form 20-F until four months after the end of each financial year, while U.S. domestic issuers that are accelerated filers are required to file their annual report on Form 10-K within 75 days after the end of each fiscal year. Foreign private issuers are also exempt from the Regulation Fair Disclosure, aimed at preventing issuers from making selective disclosures of material information. As a result of the above, you may not have the same protections afforded to shareholders of companies that are not foreign private issuers.

As a foreign private issuer and as permitted by the listing requirements of NASDAQ, we will rely on certain home country governance practices rather than the corporate governance requirements of NASDAQ.

We will be a foreign private issuer as of the effective date of this registration statement. As a result, in accordance with NASDAQ Listing Rule 5615(a)(3), we will comply with home country governance requirements and certain exemptions thereunder rather than complying with certain of the corporate governance requirements of NASDAQ.

Irish law does not require that a majority of our board of directors consist of independent directors. Our board of directors therefore may include fewer independent directors than would be required if we were subject to NASDAQ Listing Rule 5605(b)(1). In addition, we will not be subject to NASDAQ Listing Rule 5605(b)(2), which requires that independent directors must regularly have scheduled meetings at which only independent directors are present.

Our articles of association (hereinafter referred to as our Articles) provide that at any meeting of shareholders, a shareholder may designate another person to attend, speak and vote at the meeting on their behalf by proxy, but no such proxy shall be voted or acted upon at any subsequent meeting, unless the proxy expressly provides for this. Irish law does not require shareholder approval for the issuance of securities in connection with the establishment of or amendments to equity-based compensation plans for employees. To this extent, our practice varies from the requirements of NASDAQ Listing Rule 5635, which generally requires an issuer to obtain shareholder approval for the issuance of securities in connection with such events.

For an overview of our corporate governance principles, see “Description of Share Capital and Articles of Association.” As a result of the above, you may not have the same protections afforded to shareholders of companies that are not foreign private issuers.

We may lose our foreign private issuer status, which would then require us to comply with the Exchange Act’s domestic reporting regime and cause us to incur significant legal, accounting and other expenses.

We are a foreign private issuer and therefore we are not required to comply with all of the periodic disclosure and current reporting requirements of the Exchange Act applicable to U.S. domestic issuers. Losing our status as a foreign private issuer would require us to comply with all of the periodic disclosure and current reporting requirements of the Exchange Act applicable to U.S. domestic issuers. In order to maintain our current status as a foreign private issuer, either (1) a majority of our ordinary shares must be either directly or indirectly owned of record by non-residents of the United States or (2)(A) a majority of our executive officers or directors may not be United States citizens or residents, (B) more than 50% of our assets cannot be located in the United States and (C) our business must be administered principally outside the United States. If we lost this status, we would be required to comply with the Exchange Act reporting and other requirements applicable to U.S. domestic issuers, which are more detailed and extensive than the requirements for foreign private issuers. We may also be required to make changes in our corporate governance practices in accordance with various SEC and stock exchange rules. The regulatory and compliance costs to us under U.S. securities laws if we are required to comply with the reporting requirements applicable to a U.S. domestic issuer may be significantly higher than the cost we would incur as a foreign private issuer. As a result, we expect that a loss of foreign private issuer status would increase our legal and financial compliance costs and would make some activities highly time consuming and costly. We also expect that if we were required to comply with the rules and regulations applicable to U.S. domestic issuers, it would make it more difficult and expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These rules and regulations could also make it more difficult for us to attract and retain qualified members of our board of directors.

Your rights as a shareholder will be governed by Irish law and differ from the rights of shareholders under U.S. law.

We are a public limited company incorporated under the laws of Ireland. Therefore, the rights of holders of ordinary shares are governed by Irish law and by our memorandum of association and Articles. These rights differ from the typical rights of shareholders in U.S. corporations. In certain cases, facts that, under U.S. law, would entitle a shareholder in a U.S. corporation to claim damages may not give rise to a cause of action under Irish law entitling a shareholder in an Irish company to claim damages. For example, the rights of shareholders to bring proceedings against us or against our directors or officers in relation to public statements are more limited under Irish law than under the civil liability provisions of the U.S. securities laws.

You may have difficulties enforcing, in actions brought in courts in jurisdictions located outside the United States, judgments obtained in the U.S. courts under the U.S. securities laws. In particular, if you sought to bring proceedings in Ireland based on U.S. securities laws, the Irish court might consider that:

- it did not have jurisdiction;
- it was not the appropriate forum for such proceedings;
- applying Irish conflict of laws rules, U.S. laws (including U.S. securities laws) did not apply to the relationship between you and us or our directors and officers; or
- the U.S. securities laws were of a penal nature or violated Irish public policy and should not be enforced by the Irish court.

You should also be aware that Irish law does not allow for any form of legal proceedings directly equivalent to the class action available in the United States. For further information with respect to your rights as a holder of our ordinary shares, see the section of this prospectus titled “Description of Share Capital and Articles of Association.”

After the settlement of the Exchange Offer, to the extent our financial statements will be audited by a registered public accounting firm in Ireland, because the PCAOB is not currently permitted to inspect registered public accounting firms in the Republic of Ireland, including our independent registered public accounting firm, you may not benefit from such inspections.

Auditors of U.S. public companies, including our independent registered public accounting firm, are required by the laws of the United States to undergo periodic PCAOB inspections to assess their compliance with U.S. law and professional standards in connection with performance of audits of financial statements filed with the SEC. The laws of certain European Union countries, including the Republic of Ireland, do not currently permit the PCAOB to conduct inspections of accounting firms established and operating in such European Union countries. Accordingly, to the extent our financial statements will be audited by a registered public accounting firm in Ireland, the PCAOB would be prevented from fully evaluating the effectiveness of our independent registered public accounting firm’s audit procedures or quality control procedures. Unlike shareholders or potential shareholders of most U.S. public companies, our shareholders would be deprived of the possible benefits of such PCAOB inspections.

A future transfer of your ordinary shares, other than one effected by means of the transfer of book-entry interests in DTC, may be subject to Irish stamp duty.

The rate of stamp duty, when applicable, on the transfer of shares in an Irish-incorporated company is 1% of the price paid, or the market value of the shares acquired, whichever is greater. Payment of Irish stamp duty is generally a legal obligation of the transferee. We expect that most of

our ordinary shares will be traded through the Depository Trust Company, or DTC, or through brokers who hold such shares on behalf of customers through DTC. As such, the transfer of ordinary shares should be exempt from Irish stamp duty based on established practice of the Irish Revenue Commissioners. We received written confirmation from the Irish Revenue Commissioners on June 22, 2015 that a transfer of our ordinary shares held through DTC and transferred by means of a book-entry interest would be exempt from Irish stamp duty. However, if you hold your ordinary shares directly of record, rather than beneficially through DTC, or through a broker that holds your ordinary shares through DTC, any transfer of your ordinary shares may be subject to Irish stamp duty. The potential for stamp duty to arise could adversely affect the price and liquidity of our ordinary shares. In addition, the terms of our eligibility agreement with DTC will require us to provide certain indemnities relating to Irish stamp duty to third parties. If liability were to arise as a result of the indemnities provided under the terms of the eligibility agreement, we may face significant unexpected costs.

The Swedish squeeze-out process is a lengthy process to complete and may cause us to incur unanticipated costs. The delay in our acquiring full ownership of Cortendo AB could result in increased administrative costs and burdens and could adversely affect our day-to-day operations and the liquidity and market value of our shares.

This process and any delays may cause us to incur unexpected costs or result in unanticipated structuring or tax costs. Further, the act of redomiciling may impair our ability to utilize our NOLs.

As the holder of more than 90% of Cortendo AB's shares following the settlement of the Exchange Offer, we will pursue a squeeze-out process permitted under Swedish law, which will allow us to acquire the remaining shares of Cortendo AB that were not exchanged as part of the Exchange Offer. This process will be conducted by arbitration proceedings. The final arbitration award in which the squeeze-out price is determined will likely not be rendered until 12 to 18 months or more from initiation of the proceedings. We will have the possibility to request advance title to the remaining Cortendo AB shares before such time, which normally can be obtained within six to nine months from initiation of the proceedings, provided that we provide sufficient security for the final squeeze-out price and interest thereon. In such case, we would receive title to such shares and would also be required to pay a preliminary per-share squeeze-out price for the remaining Cortendo AB shares that corresponds to the value of the per-share Exchange Offer consideration, together with interest thereon. Until advance title is granted, Cortendo AB shareholders who did not participate in the Exchange Offer will hold a minority interest in Cortendo AB. After advance title has been granted, the former Cortendo AB shareholders will merely have a claim for the final squeeze-out price, reduced by the preliminary amount we paid in connection with the advance title.

The existence of minority shareholders in Cortendo AB may, among other things, make it more difficult or delay our ability to implement changes to our legal structure and interfere with our day-to-day business operations and corporate governance. For example, intra-group transfers of entities and transactions between us and our subsidiaries and affiliates, or among our subsidiaries and affiliates, will need to be carried out on market terms and on an arm's-length basis, which may impair the efficiency of our day-to-day operations. As a matter of Swedish law, minority Cortendo AB shareholders will also have the ability to request special investigations, convene general meetings of shareholders and propose agenda items for our annual general meetings. Each of these circumstances, along with other measures we may need to take to recognize the continuing legal rights of the remaining minority Cortendo AB shareholders, may result in increased costs and administrative burden.

In addition, holders of Cortendo AB shares who have chosen not to exchange their shares pursuant to the Exchange Offer will have a pro rata claim upon any dividends or other distributions payable by Cortendo AB and will be entitled to receive a proportionate share of any dividend payments or other distributions made by Cortendo AB, consequently reducing the amount of any dividend payments or other distributions that we might make to holders of our shares.

As long as these minority Cortendo AB shareholders remain after settlement of the Exchange Offer, there will be fewer of our shares outstanding than there were Cortendo AB shares outstanding prior to the settlement of the Exchange Offer. As a result, the market for and the liquidity and market value of our shares could be adversely affected.

We expect to expend cash in connection with the squeeze-out proceedings.

The actual price per share purchased pursuant to the Swedish squeeze-out proceedings will be determined by the arbitration tribunal. As a result of the squeeze-out proceedings, we may ultimately have to pay, in the aggregate, a higher price per share in order to purchase the remaining 865,026 Cortendo AB shares that are outstanding following the completion of the Exchange Offer. Such price will also under Swedish law have to be paid in cash, which will have an impact on our liquidity and cash reserves, and therefore may have an adverse effect on our financial and operational flexibility.

Anti-takeover provisions in our Articles and under Irish law could make an acquisition of us more difficult, limit attempts by our shareholders to replace or remove our current directors and management team, and limit the market price of our ordinary shares.

Our Articles contain provisions that may delay or prevent a change of control, discourage bids at a premium over the market price of our ordinary shares and adversely affect the market price of our ordinary shares and the voting and other rights of the holders of our ordinary shares. These provisions include:

- dividing our board of directors into three classes, with each class serving a staggered three-year term;
- permitting our board of directors to issue preference shares without shareholder approval, with such rights, preferences and privileges as they may designate;
- provisions which allow our board of directors to adopt a shareholder rights plan upon such terms and conditions as it deems expedient and in our best interests;
- establishing an advance notice procedure for shareholder proposals to be brought before an annual meeting, including proposed nominations of persons for election to our board of directors; and
- the ability of our board of directors to fill vacancies on our board in certain circumstances.

These provisions do not make us immune from takeovers. However, these provisions will apply even if the offer may be considered beneficial by some shareholders. In addition, these provisions may frustrate or prevent any attempts by our shareholders to replace or remove our current management team by making it more difficult for shareholders to replace members of our board of directors, which is responsible for appointing the members of our management.

Irish law differs from the laws in effect in the United States with respect to defending unwanted takeover proposals and may give our board of directors less ability to control negotiations with hostile offerors.

We are subject to the Irish Takeover Rules. Under the Irish Takeover Rules, our board of directors is not permitted to take any action that might frustrate an offer for our ordinary shares once our board of directors has received an approach that may lead to an offer or has reason to believe that such an offer is or may be imminent, subject to certain exceptions. Potentially frustrating actions such as (1) the issue of shares, options, restricted share units or convertible securities, (2) material acquisitions or disposals, (3) entering into contracts other than in the ordinary course of business or (4) any action, other than seeking alternative offers, which may result in frustration of an offer, are prohibited during the course of an offer or at any earlier time during which our board of directors has

reason to believe an offer is or may be imminent. These provisions may give our board of directors less ability to control negotiations with hostile offerors than would be the case for a corporation incorporated in the United States. We discuss these differences in the section titled “Description of Share Capital and Articles of Association.”

We are an “emerging growth company,” and we cannot be certain if the reduced reporting requirements applicable to “emerging growth companies” will make our ordinary shares less attractive to investors.

We are an “emerging growth company,” as defined in the JOBS Act. For as long as we continue to be an “emerging growth company,” we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not “emerging growth companies,” including not being required to comply with the auditor attestation requirements of Section 404, exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. As an “emerging growth company,” in our initial registration statement, we are required to report only two years of financial results and selected financial data compared to three and five years, respectively, for comparable data reported by other public companies. We could be an “emerging growth company” for up to five years, although circumstances could cause us to lose that status earlier, including if the market value of our ordinary shares held by non-affiliates exceeds \$700 million as of any June 30 before that time, in which case we would no longer be an “emerging growth company” as of the following December 31, our fiscal year end. We cannot predict if investors will find our ordinary shares less attractive because we may rely on these exemptions. If some investors find our ordinary shares less attractive as a result, there may be a less active trading market for our ordinary shares and the price of our ordinary shares may be more volatile.

MARKET AND INDUSTRY DATA

In this prospectus, we have used industry and market data obtained from our own internal estimates and research as well as from industry publications and research, surveys and studies conducted by third parties. We have compiled, extracted and reproduced industry and market data from external sources that we believe to be reliable. We caution prospective investors not to place undue reliance on the above mentioned data. Unless otherwise indicated in the prospectus, the basis for any statements regarding our competitive position is based on our own assessment and knowledge of the market in which we operate. The industry in which we operate is subject to a high degree of uncertainty and risk due to a variety of factors, including those described in the section titled “Risk Factors.” These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties and by us.

Although the industry and market data is inherently imprecise, we confirm that where information has been sourced from a third party, such information has been accurately reproduced and that as far as we are aware and are able to ascertain from information published by that third party, no facts have been omitted that would render the reproduced information inaccurate or misleading. Where information sourced from third parties has been presented, the source of such information has been identified.

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements that involve substantial risks and uncertainties. The forward-looking statements are contained principally in the sections of this prospectus titled “Prospectus Summary,” “Risk Factors,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Business.” All statements, other than statements of historical facts, contained in this prospectus, including statements regarding our future results of operations and financial position, business strategy, prospective products, product approvals, research and development costs, timing and likelihood of success, plans and objectives of management for future operations, and future results of current and anticipated products, are forward-looking statements. These statements relate to future events or to our future financial performance and involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. The words “anticipate,” “assume,” “believe,” “contemplate,” “continue,” “could,” “estimate,” “expect,” “goal,” “intend,” “may,” “might,” “objective,” “plan,” “potential,” “predict,” “project,” “positioned,” “seek,” “should,” “target,” “will,” “would,” or the negative of these terms or other similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements are based on current expectations, estimates, forecasts and projections about our business and the industry in which we operate and management’s beliefs and assumptions, are not guarantees of future performance or development and involve known and unknown risks, uncertainties and other factors. These forward-looking statements include statements regarding:

- the timing, progress and results of clinical trials for our product candidates, including statements regarding the timing of initiation and completion of clinical trials, dosing of subjects and the period during which the results of the clinical trials will become available;
- the timing, scope or likelihood of regulatory filings and approvals for our product candidates;
- our ability to successfully commercialize our product candidates;
- potential benefits of the clinical development and commercial experience of our management team;
- our ability to effectively market any product candidates that receive regulatory approval with a small, focused sale force;
- potential development and commercial synergies from having multiple product candidates for related indications;
- our commercialization, marketing and manufacturing capabilities and strategy;
- our expectation regarding the safety and efficacy of our product candidates;
- the potential clinical utility and benefits of our product candidates;
- our ability to advance our product candidates through various stages of development, especially through pivotal safety and efficacy trials;
- our estimates regarding the potential market opportunity for our product candidates;
- our expectations related to the use of proceeds from this offering;
- our strategy to in-license, acquire and develop new product candidates and our ability to execute that strategy;
- developments and projections relating to our competitors or our industry;
- our ability to become profitable;

- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- our ability to secure additional financing when needed on acceptable terms;
- the impact of government laws and regulations in the United States and foreign countries;
- the implementation of our business model, strategic plans for our business, product candidates and technology;
- our intellectual property position;
- our ability to rely on orphan drug designation for market exclusivity;
- our ability to attract or retain key employees, advisors or consultants; and
- our expectations regarding the time during which we will be an emerging growth company under the JOBS Act.

Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. As a result, any or all of our forward-looking statements in this prospectus may turn out to be inaccurate. We have included important factors in the cautionary statements included in this prospectus, particularly in the section of this prospectus titled “Risk Factors,” that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Moreover, we operate in a highly competitive and rapidly changing environment in which new risks often emerge. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make.

You should read this prospectus and the documents that we reference in this prospectus and have filed as exhibits to the registration statement of which this prospectus is a part completely and with the understanding that our actual future results may be materially different from what we expect. The forward-looking statements contained in this prospectus are made as of the date of this prospectus, and we do not assume any obligation to update any forward-looking statements except as required by applicable law.

USE OF PROCEEDS

We estimate that the net proceeds to us from the offering will be approximately \$19.3 million, after deducting the underwriting discount and estimated offering expenses payable by us. If the underwriters exercise their option to purchase additional ordinary shares in full, we estimate that the net proceeds from this offering will be approximately \$22.7 million.

As of June 30, 2015, we had cash and cash equivalents of \$54.4 million. We intend to use the net proceeds from this offering, together with our cash and cash equivalents, as follows:

- approximately \$5.0 million to fund external research and development expenses, including those related to continuation of our ongoing Phase 3 clinical trial, for COR-003 for the treatment of endogenous Cushing's syndrome;
- approximately \$5.0 million to fund external research and development expenses, including those related to nonclinical animal studies, clinical trial manufacturing and initiation of a Phase 2 or Phase 3 clinical trial, depending on advice from regulatory authorities, to support future clinical development of COR-004 for the treatment of acromegaly;
- approximately \$5.0 million to fund external research and development expenses, including those related to nonclinical animal studies, formulation development and a dose-ranging clinical trial, to support future clinical development of COR-005 for the treatment of acromegaly; and
- the remainder for working capital, general and administrative expenses, internal research and development expenses, and other general corporate purposes, including pre-commercial activities, potential in-licenses and potential acquisitions.

We believe opportunities may exist from time to time to expand our current business through the in-license or acquisition of complementary product candidates. While we have no current agreements or commitments for any specific in-licenses or acquisitions at this time, we may use a portion of the net proceeds for these purposes.

Our expected use of net proceeds from this offering represents our current intentions based upon our present plans and business condition. As of the date of this prospectus, we cannot predict with certainty all of the particular uses for the net proceeds to be received upon the completion of this offering or the amounts that we will actually spend on the uses set forth above. The amounts and timing of our actual use of net proceeds will vary depending on numerous factors, including the relative success and cost of our research, preclinical and clinical development programs, our ability to obtain additional financing, the status of and results from clinical trials, and whether regulatory authorities require us to perform additional clinical trials in order to obtain regulatory approvals. As a result, our management will have broad discretion in the application of the net proceeds of this offering, and investors will be relying on our judgment regarding the application of the net proceeds. In addition, we might decide to postpone or not pursue certain preclinical activities or clinical trials if the net proceeds from this offering and our other sources of cash are less than expected.

Based on our planned use of the net proceeds of this offering and our current cash and cash equivalents described above, we estimate that such funds will be sufficient to enable us to fund our operating expenses and capital expenditure requirements for at least the next 12 months. We have based this estimate on assumptions that may prove to be incorrect, and we could use our available capital resources sooner than we currently expect.

Pending their use, we plan to invest the net proceeds of this offering in short- and intermediate-term interest-bearing investments.

PRICE RANGE OF ORDINARY SHARES

Our ordinary shares have been quoted on the NOTC since May 2, 2002 and on the NOTC A-list since August 1, 2011 under the symbol “CORT.” Effective September 9, 2015, beneficial interests in our shares (in the form of depositary receipts) began trading on the NOTC on a split-adjusted basis under the symbol “SBBP.”

The following table sets forth the high and low prices for our ordinary shares for the calendar periods listed below. This information has been adjusted for the reverse stock split.

Share prices on the NOTC A-list are presented in Norwegian Kroner. Such over-the-counter market quotations reflect inter-dealer prices, without markup, markdown or commissions and, particularly because our ordinary shares are traded infrequently, may not necessarily represent actual transactions or a liquid trading market.

	High (NOK)	Low (NOK)	Average Daily Trading Volume
<i>Fiscal 2015</i>			
January	81.40	46.20	29,894
February	88.00	71.50	5,916
March	101.20	90.20	12,769
April	107.25	93.50	23,238
May	132.00	103.95	18,273
June	129.80	111.10	4,788
July	155.10	123.20	9,912
August	154.00	121.00	14,510
September	160.00	125.00	5,261
October (through October 14, 2015)	120.00	110.00	872
<i>Fiscal 2015</i>			
Fourth Quarter (through October 14, 2015)	120.00	110.00	872
Third Quarter	160.00	121.00	10,401
Second Quarter	132.00	93.50	15,053
First Quarter	101.20	46.20	15,961
<i>Fiscal 2014</i>			
Fourth Quarter	55.00	44.55	3,320
Third Quarter	58.30	42.90	3,604
Second Quarter	60.50	46.20	2,329
First Quarter	60.50	42.90	8,172
<i>Fiscal 2013</i>			
Fourth Quarter	53.90	42.90	8,142
Third Quarter	60.50	42.90	8,236
Second Quarter	48.40	24.20	15,723
First Quarter	30.80	26.40	2,569
Fiscal 2014	60.50	42.90	4,655
Fiscal 2013	60.50	24.20	9,791
Fiscal 2012	45.65	16.50	1,872
Fiscal 2011	53.90	9.90	1,767
Fiscal 2010	16.50	2.20	6,648

On October 14, 2015, the exchange rate between the Norwegian Kroner and the U.S. dollar was NOK 8.0982 to one U.S. dollar based on the published rate by the Norwegian central bank in effect on that date. As of October 14, 2015, the last reported sale price of our ordinary shares on the NOTC A-list was NOK 120.

DIVIDEND POLICY

Since our inception, we have never declared or paid any cash dividends on our ordinary shares and do not anticipate paying any cash dividends on our ordinary shares in the foreseeable future. We intend to retain all available funds and any future earnings to fund the development and expansion of our business. As a result, investors in our ordinary shares will benefit in the foreseeable future only if our ordinary shares appreciate in value.

Any determination to pay dividends in the future would be subject to compliance with applicable laws, including the Irish Companies Act, which requires Irish companies to have profits available for distribution equal to or greater than the amount of the proposed dividend.

CAPITALIZATION

The following table sets forth our cash and cash equivalents and our capitalization as of June 30, 2015:

- on an actual basis;
- on a pro forma basis to give effect to the settlement of the Exchange Offer, including the payment of cash for shares of Cortendo AB held by non-accredited U.S. holders; and
- on a pro forma as adjusted basis to give further effect to our issuance and sale of 2,500,000 ordinary shares in this offering at the initial public offering price of \$10.00 per share, after deducting the underwriting discount and estimated offering expenses payable by us.

	As of June 30, 2015		
	Actual	Pro Forma	Pro Forma As Adjusted
	(in thousands, except share and per share data)		
Cash and cash equivalents	\$ 54,387	\$ 53,975	\$ 73,227
Shareholders' equity (deficit):			
Common stock, par value \$0.01 per share: 600,000,000 shares authorized, 18,808,958 shares issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro forma as adjusted	\$ 188	\$ —	\$ —
Ordinary shares, par value \$0.01 per share: no shares authorized, issued or outstanding, actual; 600,000,000 shares authorized, pro forma and pro forma as adjusted; 18,705,382 shares issued and outstanding, pro forma, and 21,205,382 shares issued and outstanding, pro forma as adjusted	—	187	212
Additional paid-in capital	147,838	146,812	166,039
Accumulated deficit	(60,740)	(60,740)	(60,740)
Non-controlling interest	—	615	615
Total shareholders' equity	87,286	86,874	106,126
Total capitalization	\$ 87,286	\$ 86,874	\$106,126

You should read this table together with our financial statements and the related notes appearing at the end of this prospectus and the sections of this prospectus titled “Selected Consolidated Financial Information” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations.”

The table above does not include:

- 2,002,593 ordinary shares issuable upon the exercise of options outstanding as of June 30, 2015 at a weighted average exercise price of \$12.40 per ordinary share;
- 127,363 ordinary shares issuable upon the exercise of stock options that were awarded to our non-employee directors, contingent upon the pricing of this offering, under our new Non-Employee Director Equity Compensation Plan, at an exercise price equal to the higher of the initial public offering price per ordinary share and the closing price of our ordinary shares on the NOTC on September 22, 2015, which was NOK 145 per ordinary share, equivalent to a price of \$17.55 per share, assuming the exchange rate of NOK 8.2604 per U.S. dollar on September 22, 2015;
- 218,091 ordinary shares reserved for future issuance under our Non-Employee Director Equity Compensation Plan; and
- 1,081,818 ordinary shares available for future issuance under our 2015 equity incentive plan.

DILUTION

If you invest in our ordinary shares, your interest will be diluted to the extent of the difference between the initial public offering price per ordinary share and the pro forma as adjusted net tangible book value per ordinary share after this offering.

At June 30, 2015, we had a net tangible book value of \$43.5 million, corresponding to a net tangible book value of \$2.31 per ordinary share. Net tangible book value per share represents the amount of our total assets less our total liabilities, excluding intangible assets, divided by the total number of our ordinary shares outstanding at such date.

At June 30, 2015, we had a pro forma net tangible book value of \$43.1 million, corresponding to a pro forma net tangible book value of \$2.30 per ordinary share. Pro forma net tangible book value per share represents the amount of our total assets less our total liabilities, excluding intangible assets, divided by the total pro forma number of our ordinary shares outstanding at such date, after giving effect to the settlement of the Exchange Offer.

After giving further effect to our issuance and sale of 2,500,000 ordinary shares in this offering at the initial public offering price of \$10.00 per share, after deducting the underwriting discount and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of June 30, 2015 would have been \$62.3 million, or \$2.94 per ordinary share. This represents an immediate increase of \$0.64 in pro forma as adjusted net tangible book value per share to existing shareholders and immediate dilution of \$7.06 in pro forma as adjusted net tangible book value per ordinary share to new investors purchasing ordinary shares in this offering.

The following table illustrates this dilution to new investors purchasing ordinary shares in the offering.

Initial public offering price per ordinary share		\$10.00
Net tangible book value per ordinary share at June 30, 2015	\$ 2.31	
Decrease in net tangible book value per ordinary share attributable to pro forma adjustments	<u>(0.01)</u>	
Pro forma net tangible book value per ordinary share at June 30, 2015	2.30	
Increase in net tangible book value per ordinary share attributable to new investors	<u>0.64</u>	
Pro forma as adjusted net tangible book value per ordinary share after the offering		<u>2.94</u>
Dilution per ordinary share to new investors		<u>\$ 7.06</u>

If the underwriters were to exercise their option to purchase additional ordinary shares in full, the pro forma as adjusted net tangible book value per ordinary share after the offering would be \$3.05 per ordinary share, and the dilution per ordinary share to new investors would be \$6.95 per ordinary share.

The following table summarizes, on the pro forma as adjusted basis described above as of June 30, 2015, the differences between the number of ordinary shares purchased from us, the total consideration and the average price per ordinary share paid by existing shareholders and by investors

participating in this offering, before deducting the underwriting discount and estimated offering expenses.

	Ordinary Shares Purchased		Total Consideration (mill)		Average Price Per Share
	Number	%	Amount	%	
Existing shareholders	18,705,382	88%	\$114.1	82%	\$ 6.10
New investors	2,500,000	12	25.0	18	10.00
Total	<u>21,205,382</u>	<u>100%</u>	<u>\$139.1</u>	<u>100%</u>	

If the underwriters exercise their option to purchase additional ordinary shares in full, the following will occur:

- the percentage of our ordinary shares held by existing shareholders will decrease to 87% of the total number of our ordinary shares outstanding after this offering; and
- the percentage of our ordinary shares held by new investors will increase to 13% of the total number of our ordinary shares outstanding after this offering.

The above discussion and tables are based on our actual ordinary shares outstanding as of June 30, 2015 and exclude:

- 2,002,593 ordinary shares issuable upon the exercise of options outstanding as of June 30, 2015 at a weighted average exercise price of \$12.40 per ordinary share;
- 127,363 ordinary shares issuable upon the exercise of stock options that were awarded to our non-employee directors, contingent upon the pricing of this offering, under our new Non-Employee Director Equity Compensation Plan, at an exercise price equal to the higher of the initial public offering price per ordinary share and the closing price of our ordinary shares on the NOTC on September 22, 2015, which was NOK 145 per ordinary share, equivalent to a price of \$17.55 per share, assuming the exchange rate of NOK 8.2604 per U.S. dollar on September 22, 2015;
- 218,091 ordinary shares reserved for future issuance under our Non-Employee Director Equity Compensation Plan; and
- 1,081,818 ordinary shares available for future issuance under our 2015 equity incentive plan.

To the extent that outstanding options are exercised, you will experience further dilution. In addition, we may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of these securities may result in further dilution to our shareholders.

Certain of our existing shareholders that beneficially own more than 5% of our ordinary shares and their affiliates have indicated an interest in purchasing up to an aggregate of \$20.0 million of our ordinary shares in this offering at the initial public offering price per share. Based on the initial public offering price of \$10.00 per share, these entities would purchase up to an aggregate of 2,000,000 of the 2,500,000 shares in this offering based on these indications of interest. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters may determine to sell more, less or no shares in this offering to any of these entities, or any of these entities may determine to purchase more, less or no shares in this offering. The foregoing discussion and tables do not reflect any potential purchases by these entities or their affiliates.

SELECTED CONSOLIDATED FINANCIAL INFORMATION

The following tables set forth selected consolidated historical financial data as of, and for the periods ended on, the dates indicated. We have derived the consolidated statements of operations data for the years ended December 31, 2013 and 2014 and the consolidated balance sheet data as of December 31, 2013 and 2014 from our audited consolidated financial statements included elsewhere in this prospectus. The consolidated statements of operations data for the six months ended June 30, 2014 and 2015 and the consolidated balance sheet data as of June 30, 2015 have been derived from our unaudited consolidated financial statements included elsewhere in this prospectus. In the opinion of our management, the unaudited data reflects all adjustments, consisting of normal and recurring adjustments, necessary for the fair statement of results as of and for these periods. You should read this data together with our audited consolidated financial statements and the related notes included elsewhere in this prospectus and the sections in this prospectus entitled “Management’s Discussion and Analysis of Financial Condition and Results of Operations.” Our historical results for any prior period are not indicative of our future results and results of interim periods are not necessarily indicative of the results for the entire year.

We have prepared the unaudited consolidated financial information set forth below on the same basis as our audited consolidated financial statements. Our audited consolidated financial statements have been prepared in accordance with U.S. GAAP and are presented in U.S. dollars except where otherwise indicated.

Strongbridge Biopharma plc became the parent company of Cortendo AB following the settlement of the Exchange Offer, and for financial reporting purposes the historical consolidated financial statements of Cortendo AB became the historical consolidated financial statements of Strongbridge Biopharma plc and its subsidiaries as a continuation of the predecessor.

	Year Ended December 31,		Six Months Ended June 30,	
	2013	2014	2014	2015
(in thousands, except share and per share data)				
Consolidated Statement of Operations Data:				
Operating expenses:				
Research and development	\$ 2,534	\$ 5,844	\$ 2,460	\$ 10,218
General and administrative	2,658	4,588	1,298	12,620
Total operating expenses	5,192	10,432	3,758	22,838
Operating loss	(5,192)	(10,432)	(3,758)	(22,838)
Other income (expense), net:				
Foreign exchange loss	(570)	(204)	165	(314)
Other income, net	282	486	166	(543)
Total other income (expense), net	(288)	282	331	(857)
Loss before income taxes	(5,480)	(10,150)	(3,427)	(23,695)
Income tax benefit	93	480	225	178
Net loss	(5,387)	(9,670)	(3,202)	(23,517)
Net loss attributable to non-controlling interest . .	92	—	—	—
Net loss attributable to Strongbridge	\$ (5,295)	\$ (9,670)	\$ (3,202)	\$ (23,517)
Net loss attributable to common shareholders, basic and diluted	\$ (5,295)	\$ (9,670)	\$ (3,202)	\$ (23,517)
Net loss per share attributable to common shareholders, basic and diluted ⁽¹⁾	\$ (0.88)	\$ (1.20)	\$ (0.40)	\$ (1.75)
Weighted-average shares used in computing net loss per share attributable to common shareholders, basic and diluted	6,017,895	8,043,175	7,939,608	13,433,712

(1) See note 2 to our unaudited and audited consolidated financial statements included elsewhere in this prospectus for an explanation of the method used to calculate basic and diluted net loss per share attributable to common shareholders and basic and diluted weighted-average shares outstanding used to calculate the per share data.

	As of December 31,		As of
	2013	2014	June 30, 2015
(in thousands)			
Consolidated Balance Sheet Data:			
Cash and cash equivalents	\$14,897	\$15,632	\$ 54,387
Total assets	22,569	23,689	100,912
Total liabilities	4,746	4,868	13,626
Total shareholders' equity	17,823	18,821	87,286

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion summarizes the significant factors affecting the operating results, financial condition, liquidity and cash flows of our company as of and for the periods presented below. The following discussion and analysis should be read in conjunction with "Selected Consolidated Financial Information" and the financial statements and the related notes thereto included elsewhere in this prospectus. All share amounts and per share amounts have been retroactively adjusted, where applicable, to reflect the Exchange Offer, which settled on September 8, 2015, and the 1-for-11 reverse stock split of our ordinary shares, which was effected on September 8, 2015, immediately following the settlement of the Exchange Offer. The statements in this discussion regarding industry outlook, our expectations regarding our future performance, liquidity and capital resources and all other non-historical statements in this discussion are forward-looking statements and are based on the beliefs of our management, as well as assumptions made by, and information currently available to, our management. Actual results could differ materially from those discussed in or implied by forward-looking statements as a result of various factors, including those discussed below and elsewhere in this prospectus, particularly in the section titled "Risk Factors."

Overview

We are a biopharmaceutical company focused on the development, in-licensing, acquisition and eventual commercialization of multiple complementary products and product candidates within franchises that target rare diseases. Our primary focus has been to build our rare endocrine franchise, which includes COR-003 for the treatment of endogenous Cushing's syndrome, and COR-004 and COR-005 for the treatment of acromegaly. Endogenous Cushing's syndrome and acromegaly are two rare diseases with a high unmet need for innovative treatment options. Given the well-identified and concentrated prescriber base addressing our target markets, we believe we can use a small, focused sales force to effectively market our products, if approved, in the United States, the European Union and other key global markets. We believe that our ability to execute on this strategy is enhanced by the significant clinical development and commercial experience of key members of our management team. We also intend to identify and in-license or acquire products or product candidates that would be complementary to our existing rare endocrine franchise or that would form the basis for new rare disease franchises. We believe this approach will enable us to maximize our commercial potential by further leveraging our existing resources and expertise.

We have never been profitable and have incurred net losses since our inception in 1996. Our operations to date have been focused on identifying, in-licensing, acquiring and developing our product candidates, organizing and staffing our company, business planning and raising capital. We have funded our operations primarily through equity offerings. We incurred a net loss of \$5.3 million and \$9.7 million for the years ended December 31, 2013 and 2014, respectively, and \$3.2 million and \$23.5 million for the six months ended June 30, 2014 and 2015, respectively. At June 30, 2015, our accumulated deficit was \$60.7 million.

On February 10, 2015, following shareholder approval of the share purchase agreement which we entered into on January 12, 2015, we entered into a share purchase agreement with investors whereby we issued 4,761,078 common shares for \$25.8 million, net of transaction costs.

On May 13, 2015, we entered into an exclusive license agreement with Antisense Therapeutics Limited, or Antisense Therapeutics, that provides us with development and commercialization rights to Antisense Therapeutics' product candidate, ATL1103, for endocrinology applications. We refer to this product candidate as COR-004. Under the terms of the agreement, we provided Antisense Therapeutics with an initial upfront license payment of \$3.0 million in cash, and we also invested \$2.0 million in Antisense Therapeutics equity. We may become obligated to make additional payments, contingent upon achieving specific development and commercialization milestones, of up to \$105.0 million over the

lifetime of the agreement. We may also be required to make royalty payments based on a percentage, ranging from the mid-single digits to the mid-teens, of net sales of COR-004 during the period that we are selling COR-004, if approved. We will be responsible for the future clinical development of COR-004 in endocrinology applications and for the funding of associated future development, regulatory and drug manufacture costs. Antisense Therapeutics will retain commercialization rights for COR-004 in endocrinology applications in Australia and New Zealand as well as worldwide rights for COR-004 in indications other than endocrinology, and may utilize any new COR-004 data generated by us in pursuing these other indications, subject to specified terms and conditions set forth in our license agreement with Antisense Therapeutics.

On June 29 and 30, 2015, we raised \$33.2 million in aggregate gross proceeds in a private placement of common shares, the proceeds of which we expect to use primarily for the continued development of COR-003, along with the planned development of our two new programs, COR-004 and COR-005, and for general corporate purposes. The subscription price was \$14.54 per share and we issued 2,284,414 new shares to the investors.

On June 30, 2015, we acquired from Aspireo Pharmaceuticals Ltd., an Israeli company, its product candidate, DG3173. We refer to this product candidate as COR-005. Under the terms of the acquisition agreement, we issued to Aspireo Pharmaceuticals 2,062,677 common shares, which had a value of \$33.2 million on June 30, 2015. In connection with this acquisition, we made a payment to the Office of the Chief Scientist of the Israeli Ministry of Economy, or OCS, in the amount of \$3.0 million, which represents the repayment of amounts previously granted by OCS to Aspireo Pharmaceuticals, plus interest, that were used in support of research and development conducted by Aspireo Pharmaceuticals for the development of DG3173.

Financial Operations Overview

The following discussion sets forth certain components of our statements of operations as well as factors that impact those items.

Revenues

We have not generated any revenue during the periods presented. Our ability to generate product revenue and become profitable depends upon our ability to obtain regulatory approval for and to successfully commercialize our product candidates.

Research and Development Expenses

Our research and development expenses consist primarily of costs incurred in connection with the development of our product candidates, including:

- personnel-related costs, such as salaries, bonuses, benefits, travel and other related expenses, including stock-based compensation;
- expenses incurred under our agreements with CROs, clinical sites, contract laboratories, medical institutions and consultants that plan and conduct our preclinical studies and clinical trials, including, in the case of consultants, stock-based compensation;
- costs associated with regulatory filings;
- upfront and milestone payments under in-license agreements with third parties;
- costs of acquiring preclinical study and clinical trial materials, and costs associated with formulation and process development;
- depreciation, maintenance and other facility-related expenses; and

- costs to secure an exclusive license agreement with Antisense Therapeutics.

We expense all research and development costs as incurred. Clinical development expenses for our product candidates are a significant component of our current research and development expenses as we progress our product candidates into and through clinical trials. Product candidates in later stage clinical development generally have higher research and development costs than those in earlier stages of development, primarily due to increased size and duration of the clinical trials. We recognize costs for each grant project, preclinical study or clinical trial that we conduct based on our evaluation of the progress to completion, using information and data provided to us by our external research and development vendors and clinical sites.

We have received funding from research and development grants from the U.S. federal Small Business Innovation Research/Small Business Technology Transfer program. We record such funding as a reduction to our research and development expenses.

Through the first half of 2014, we were focused on product candidates that are now outside the scope of our strategic focus, specifically the development of Crespine, an osteoarthritis program, and a next generation cortisol inhibitor, or NGCI, program. By the end of 2014, we changed our strategic focus to rare endocrine diseases and other rare diseases, specifically the development of COR-003. As a result, we significantly reduced activities to develop the Crespine and NGCI programs. We returned our commercial rights to Crespine to the originator in the first half of 2014. We expect to spend only such amounts as are necessary to maintain our intellectual property on the NGCI program.

We incurred research and development expenses of \$2.5 million and \$5.8 million for the years ended December 31, 2013 and 2014, respectively, and \$2.5 and \$10.2 for the six months ended June 30, 2014 and 2015, respectively.

We expect our research and development expenses to increase in absolute dollars in the future as we continue to in-license or acquire product candidates and as we advance our existing and any future product candidates into and through clinical trials and pursue regulatory approval of our product candidates. The process of conducting the necessary clinical research to obtain regulatory approval of a product candidate is costly and time consuming. The probability that any of our product candidates receives regulatory approval and eventually is able to generate revenue depends on a variety of factors, including the quality of our product candidates, early clinical data, investment in our clinical program, competition, manufacturing capability and commercial viability. As a result of these uncertainties, we are unable to determine the duration and completion costs of our research and development projects or if, when and to what extent we will generate revenue from the commercialization and sale of any of our product candidates, if approved. We may never succeed in achieving regulatory approval for any of our product candidates.

We do not allocate personnel-related research and development costs, including stock-based compensation or other indirect costs, to specific programs, as they are deployed across multiple projects under development.

General and Administrative Expenses

General and administrative expenses include personnel costs, costs for outside professional services and other allocated expenses. Personnel costs consist of salaries, bonuses, benefits, travel and stock-based compensation. Outside professional services consist of legal, accounting and audit services, commercial evaluation and strategy services, and other consulting services. We expect to incur additional general and administrative costs as a result of operating as a public company, including expenses related to compliance with the rules and regulations of the SEC and those of any national securities exchange on which our securities are traded, additional insurance expenses, investor relations activities and other administrative and professional services. We also expect to incur additional expenses

related to in-licenses, acquisitions or similar transactions that we may pursue as part of our strategy, including legal, accounting and audit services and other consulting fees.

Other Income (Expense), Net

Other income (expense), net, consists of interest income generated from our cash and cash equivalents, gains from the revaluation of foreign currency forward contracts and foreign exchange gains and losses.

Our consolidated financial statements are reported in U.S. dollars, which is also our functional currency. Transactions in foreign currencies are translated into our functional currency at the rate of exchange prevailing at the date of the transaction. Any monetary assets and liabilities arising from these transactions are translated into our functional currency at exchange rates prevailing at the balance sheet date or on settlement. Resulting gains and losses are recorded in foreign currency gain (loss) in other income (expense) in our consolidated statements of operations.

Historically, our cash and cash equivalents have been held primarily in foreign currencies. However, most of our expenses have been U.S. dollar denominated. To reduce our currency exposure, we used a hedging program from the fourth quarter of 2013 through the second quarter of 2015. The foreign currency forward contracts used in our hedging program were not entered into for speculative purposes and, although we believe they served as effective economic hedges, we did not seek to qualify for hedging accounting. In 2014, our operations continued to shift to the United States, but a large portion of our cash and cash equivalents were still held in foreign currencies. As of June 30, 2015, all of our forward contracts have expired.

Critical Accounting Policies and Significant Judgments and Estimates

This management's discussion and analysis of our financial condition and results of operations is based on our interim consolidated financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these interim consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. The consolidated statements of operations data for the six months ended June 30, 2014 and 2015 are unaudited interim consolidated financial statements. You should also read this data together with the expanded information about our critical accounting policies and estimates provided in "Management's Discussion and Analysis of Financial Condition and Results of Operations," for the year ended December 31, 2014 included elsewhere in this prospectus. There have been no material changes to our critical accounting policies and estimates from the information provided in our audited consolidated financial statements for the year ended December 31, 2014.

Business Combinations

When acquiring new enterprises over which we obtain control, the acquisition method is applied. Under this method, we identify assets and liabilities of these enterprises and measure them at fair value at the acquisition date. Allowance is made for the tax effect of the adjustments made.

The excess of the consideration transferred, the amount of the non-controlling interest in the acquiree and the acquisition date fair value of previous equity interest in the acquiree over the fair value of the identifiable net assets acquired is recorded as goodwill.

In-Process Research and Development

Purchased identifiable intangible assets with indefinite lives, such as our in-process research and development, are evaluated for impairment annually in accordance with our policy and whenever events or changes in circumstances indicate that it is more likely than not that the fair value of these assets has been reduced. To test these assets for impairment, we compare the fair value of the asset to its carrying value. The method we use to estimate the fair value measurements of indefinite-lived intangible assets is based on the income approach. For the impairment analysis for the year ended December 31, 2014, significant unobservable inputs used in the income approach valuation method included a discount rate of 15.5%, a royalty rate of 10% and various probabilities of product candidate advancement from one clinical trial phase to the next. The probabilities of product candidate advancement we used were based on standalone statistical analysis on a phase-by-phase basis. There is no correlation between the probabilities of advancement in one phase to the probability of advancement in the prior phase. For purposes of our analysis for the year ended December 31, 2014, we applied the following approximate probabilities of product candidate advancement by phase: 67% probability of advancing from Phase 1 to Phase 2, 37% probability of advancing from Phase 2 to Phase 3, and 64% probability of advancing from Phase 3 to regulatory approval. An increase (decrease) in the estimated royalty rate of 2% assuming no change in discount rates or probability of success rates would result in a significantly higher (lower) fair value measurement. Significant increases in the discount rate up to 31%, assuming no changes in royalty rates and probability of success rates, would result in a significantly lower fair value measurement.

During the first half of 2015, as a result of our acquisition of Aspireo Pharmaceuticals Ltd.'s product candidate DG3173, our in-process research and development increased by \$31.3 million.

As of June 30, 2015, there were no events or changes in circumstances indicating possible impairment.

Goodwill

We test goodwill for impairment on an annual basis or whenever events occur that may indicate possible impairment. This analysis requires us to make a series of critical assumptions to (1) evaluate whether any impairment exists and (2) measure the amount of impairment.

Because we have one operating segment, when testing for a potential impairment of goodwill, we are required to estimate the fair value of our business as a whole and determine the carrying value. If the estimated fair value is less than the carrying value of our business, then we are required to estimate the fair value of all identifiable assets and liabilities in a manner similar to a purchase price allocation for an acquired business. Only after this process is completed can the goodwill impairment be determined, if any.

To estimate the fair value of the business, a market-based approach is applied, utilizing our share price on the NOTC A-list as well as the price of shares issued in private placements, such as those completed in September 2013 and in October 2014. We did not record a charge for impairment for the years ended December 31, 2013 and 2014.

During the first half of 2015, as a result of our acquisition of Aspireo Pharmaceuticals Ltd.'s product candidate DG3173, our goodwill increased by \$5.1 million.

As of June 30, 2015, there were no events or changes in circumstances indicating possible impairment.

Research and Development Costs and Expenses

Research and development costs are expensed as incurred. We recognize costs for certain development activities based on an evaluation of the progress to completion of specific tasks using information and data provided to us by our vendors and our clinical sites. We determine accrual estimates through financial models that take into account discussion with applicable personnel and service providers as to the progress or state of completion of clinical trials. Our preclinical study and clinical trial accrued liabilities and prepaid assets are dependent, in part, upon the receipt of timely and accurate reporting from CROs and other third-party vendors. Although we do not expect our estimates to differ materially from amounts we actually incur, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in our reporting amounts that are too high or too low for any particular period. When contracts for outside research products or testing require advance payment, they are recorded on our consolidated balance sheets as prepaid items and expensed when the service is provided or reaches a specific milestone outlined in the contract.

Stock-Based Compensation

We account for stock-based compensation awards in accordance with the Financial Accounting Standards Board, or FASB, *ASC Topic 718, Compensation—Stock Compensation (ASC 718)*. ASC 718 requires all stock-based payments, including grants of stock options and restricted stock and modifications to existing stock options, to be recognized in the consolidated statements of operations based on their fair values. The exercise price of stock options is determined by management by taking into account the trading price of our ordinary shares on the NOTC A-list, as well as other factors, including any private placements of our ordinary shares, but in no event has the exercise price of any stock option been less than the market price on the NOTC A-list on the date of grant.

Our stock-based awards are subject to either service-based or performance-based vesting conditions. Vesting of certain awards could also be accelerated upon achievement of defined market-based vesting conditions. We measure employee stock-based awards at grant-date fair value. We measure non-employee stock-based awards at the date the performance is complete. We have also issued several stock options with exercise prices denominated in a foreign currency that are required to be accounted for as liabilities. These options are measured at the date they are settled (exercised). We account for non-employee and liability-classified stock-based awards based on the then-current fair values at each financial reporting date until the relevant measurement date occurs.

We record compensation expense for service-based awards over the vesting period of the award on a straight-line basis. Compensation expense related to awards with performance-based vesting conditions is recognized over the requisite service period using the accelerated attribution method to the extent achievement of the performance condition is probable. Compensation expense for awards with service- and market-based vesting conditions is recognized using the accelerated attribution method over the shorter of the requisite service period or the implied period associated with achievement of the market-based vesting provisions.

We estimate the fair value of our option awards using the Black-Scholes option pricing model, which requires the input of subjective assumptions, including:

- **Expected Volatility.** Due to the lack of historical and implied volatility data of our ordinary shares, we based our estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded. We selected companies with comparable characteristics to us, including enterprise value, risk profiles and positions within the industry, and with historical share price information sufficient to meet the expected term of the stock-based awards. We compute historical volatility data using the daily closing prices

for the selected companies' shares during the equivalent period of the calculated expected term of the stock-based awards.

- **Expected Term of the Award.** We have estimated the expected term of employee service-based stock options using the “simplified” method, whereby the expected term equals the arithmetic average of the vesting term and the original contractual term of the option, due to our lack of sufficient historical data. We have estimated the expected term of employee awards with service and market conditions using a Monte-Carlo simulation model. This approach involves generating random stock-price paths through a lattice-type structure. Each path results in a certain financial outcome, such as accelerated vesting or specific option payout. We have estimated the expected term of nonemployee service- and performance-based awards based on the remaining contractual term of such awards.
- **Risk-Free Interest Rate.** The risk-free interest rates for periods within the expected term of the options are based on the Swedish Government Bond rate with a maturity date commensurate with the expected term of the associated award.
- **Expected Dividends.** We have never paid, and do not expect to pay, dividends in the foreseeable future. Therefore, the expected dividend yield was assumed to be zero.

We are also required to estimate forfeitures at the time of grant, and revise those estimates in subsequent periods if actual forfeitures differ from our estimates. We record stock-based compensation expense only for those awards that are expected to vest. To the extent that actual forfeitures differ from our estimates, the differences are recorded as a cumulative adjustment in the period the estimates were revised. Historical forfeitures have been insignificant.

Income Taxes

We use the liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on the differences between the financial reporting and tax bases of assets and liabilities, and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. We assess the likelihood that the resulting deferred tax assets will be realized. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized.

We have evaluated the positive and negative evidence bearing upon the realizability of our deferred tax assets. Based on our history of operating losses, we have concluded that it is more likely than not that the benefit of our deferred tax assets, other than those attributable to BioPancreate, will not be realized. The deferred tax assets primarily comprised of Swedish and U.S. federal and state tax net operating losses and tax credit carryforwards. Utilization of the net operating loss and tax credit carryforwards may be subject to an annual limitation due to historical or future ownership percentage change rules provided by the Internal Revenue Code of 1986, as amended, and similar state and Swedish provisions. The annual limitation may result in the expiration of net operating loss and tax credit carryforwards before their utilization.

The JOBS Act

As an “emerging growth company” under the JOBS Act, we can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an “emerging growth company” to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this extended transition period and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies

We are in the process of evaluating the benefits of relying on other exemptions and reduced reporting requirements under the JOBS Act. Subject to certain conditions, as an “emerging growth company,” we intend to rely on certain of these exemption including, without limitation, the exemptions from providing an auditor’s attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act of 2002. We will remain an “emerging growth company” until the earliest of: (1) the last day of the fiscal year in which we have total annual gross revenues of \$1 billion or more; (2) the last day of the fiscal year following the fifth anniversary of the date of the completion of this offering; (3) the date on which we have issued more than \$1 billion in nonconvertible debt during the previous three years; and (4) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

In connection with the audits of our 2013 and 2014 financial statements, which were completed concurrently, our independent registered public accounting firm identified a material weakness, primarily related to the lack of sufficient and skilled resources with U.S. GAAP and SEC reporting knowledge for the purpose of timely and reliable financial reporting. We are working to remediate the material weakness and are taking numerous steps and plan to take additional steps to remediate the underlying causes of the material weakness. We have recently hired a new full-time chief financial officer, and plan to develop and implement formal policies, processes and documentation procedures relating to our financial reporting of the company. The actions that we are taking are subject to ongoing senior management review, as well as audit committee oversight.

Results of Operations

Comparison of the Six Months Ended June 30, 2014 and 2015

The following table sets forth our results of operations for the six months ended June 30, 2014 and 2015:

	Six Months Ended June 30,		Change
	2014	2015	\$
	(in thousands)		
Operating expenses:			
Research and development	\$ 2,460	\$ 10,218	\$ 7,758
General and administrative	1,298	12,620	11,322
Total operating expenses	<u>3,758</u>	<u>22,838</u>	<u>19,080</u>
Operating loss	(3,758)	(22,838)	(19,080)
Other income (expense), net	331	(857)	(1,188)
Loss before income taxes	(3,427)	(23,695)	(20,268)
Income tax benefit	225	178	(47)
Net loss attributable to Strongbridge	<u><u>\$ (3,202)</u></u>	<u><u>\$ (23,517)</u></u>	<u><u>\$ (20,315)</u></u>

Research and Development Expenses

The following table summarizes our research and development expenses during the six months ended June 30, 2014 and 2015:

	Six Months Ended June 30,		Change
	2014	2015	\$
	(in thousands)		
Clinical development	\$1,515	\$ 3,694	\$2,179
Preclinical development	512	258	(254)
License fee	—	3,898	3,898
Compensation and related personnel costs	—	1,548	1,548
Outside professional services and other	433	820	387
Total research and development expenses	<u>\$2,460</u>	<u>\$10,218</u>	<u>\$7,758</u>

Research and development expenses were \$10.2 million for the six months ended June 30, 2015, an increase of \$7.8 million compared to the six months ended June 30, 2014. The increase was attributed to a \$3.9 million increase related to the Antisense Therapeutics license fee, \$2.2 million increase in clinical development expenses mainly associated with ongoing clinical trials for COR-003, and a \$0.3 million decrease in preclinical costs primarily related to the reduction in activities related to the Crespine and NGCI programs in mid-2014. Compensation and related personnel costs increased by \$1.5 million for the six months ended June 30, 2015 as compared to the six months ended June 30, 2014, due to the hiring of research and development personnel. Outside professional services expense increased by \$0.4 million due to an increase in the use of consultants in 2015 used for increased research and development activities.

General and Administrative Expenses

The following table summarizes our general and administrative expenses during the six months ended June 30, 2014 and 2015:

	Six Months Ended June 30,		Change
	2014	2015	\$
	(in thousands)		
Outside professional services	\$ 957	\$ 9,055	\$ 8,098
Compensation and related personnel costs	60	2,956	2,896
Facility costs	33	126	93
Travel and other	248	483	235
Total general and administrative expenses	<u>\$1,298</u>	<u>\$12,620</u>	<u>\$11,322</u>

General and administrative expenses were \$12.6 million for the six months ended June 30, 2015, an increase of \$11.3 million compared to the six months ended June 30, 2014. The increase was primarily due to a \$8.1 million increase in outside professional services, which consisted of mostly legal, accounting and consulting fees, related to the redomicile of the Company, due diligence expenses for the Asperio asset acquisition and other business development activities, activities related to this offering, general corporate matters, including market analysis, communications and investor relations efforts, as well an increase in other legal and accounting costs. Compensation and related personnel costs increased by \$2.9 million for the six months ended June 30, 2015 as compared to the six months ended June 30, 2014, due to increased hiring of administrative personnel. Facility costs, travel and other general and administrative costs increased by \$0.3 million for the six months ended June 30, 2015 as

compared to the six months ended June 30, 2014, primarily as a result of the Trevoise, Pennsylvania facility sublease and the hiring of additional personnel.

Other Income (Expense), Net

The following table summarizes our other income (expense), net, during the six months ended June 30, 2014 and 2015:

	Six Months Ended June 30,		Change
	2014	2015	\$
	(in thousands)		
Foreign exchange gain (loss)	\$165	\$(314)	\$ (479)
Other income, net	166	(543)	(709)
Total other income (expense), net	<u>\$331</u>	<u>\$(857)</u>	<u>\$(1,188)</u>

Other income (expense), net, changed from income of \$0.3 million in 2014 to expense of \$0.9 million in 2015. The change was primarily due to fluctuations in foreign exchange rates against the U.S. dollar, together with losses from expired forward currency contracts. In addition, other income (expense), net included a \$0.1 million charge for the impairment of the leased Radnor, Pennsylvania facility.

Income Tax Benefit

We recorded income tax benefit of \$0.2 million for the six months ended June 30, 2014 and 2015, due to the generation of U.S. state and federal net operating loss carryforwards and federal tax credit carryforwards. The income tax benefit for U.S. state and federal net operating loss carryforwards and federal tax credit carryforwards has been recognized to the extent it is supported by the deferred tax liability recorded in connection with the acquisition of BioPancreate.

Comparison of the Years Ended December 31, 2013 and 2014

The following table sets forth our results of operations for the years ended December 31, 2013 and 2014.

	Year Ended December 31,		Change
	2013	2014	\$
	(in thousands)		
Operating expenses:			
Research and development	\$ 2,534	\$ 5,844	\$ 3,310
General and administrative	2,658	4,588	1,930
Total operating expenses	<u>5,192</u>	<u>10,432</u>	<u>5,240</u>
Operating loss	(5,192)	(10,432)	(5,240)
Other (expense) income, net	(288)	282	570
Loss before income taxes	(5,480)	(10,150)	(4,670)
Income tax benefit	93	480	387
Net loss	(5,387)	(9,670)	(4,283)
Net loss attributable to non-controlling interest	92	—	(92)
Net loss attributable to Strongbridge	<u>\$(5,295)</u>	<u>\$(9,670)</u>	<u>\$(4,375)</u>

Research and Development Expenses

The following table summarizes our research and development expenses during the years ended December 31, 2013 and 2014:

	Year Ended December 31,		Change
	2013	2014	\$
	(in thousands)		
Clinical development	\$ 975	\$4,023	\$3,048
Preclinical development	541	894	353
Compensation and related personnel costs	117	164	47
Outside professional services and other	901	763	(138)
Total research and development expenses	<u>\$2,534</u>	<u>\$5,844</u>	<u>\$3,310</u>

Research and development expenses were \$5.8 million for the year ended December 31, 2014, an increase of \$3.3 million compared to the year ended December 31, 2013. The increase was primarily attributed to a \$3.0 million increase in clinical development expenses mainly associated with ongoing clinical trials for COR-003, and a \$0.8 million increase in preclinical costs. The increase in preclinical development costs was offset in part by a decrease of \$0.4 million related to the reduction in activities related to the Crespine and NGCI programs in 2014 and a reduction in the use of consultants in 2014 due to the hiring of additional internal research and development personnel.

In 2013 and 2014, we recognized \$0.2 million and \$0, respectively, from U.S. federal government grants to support our research and development activities of BioPancreate as a reduction to our preclinical development expenses.

General and Administrative Expenses

The following table summarizes our general and administrative expenses during the years ended December 31, 2013 and 2014:

	Year Ended December 31,		Change
	2013	2014	\$
	(in thousands)		
Outside professional services	\$2,134	\$3,122	\$ 988
Compensation and related personnel costs	268	904	636
Facility costs	60	105	45
Travel and other	196	457	261
Total general and administrative expenses	<u>\$2,658</u>	<u>\$4,588</u>	<u>\$1,930</u>

General and administrative expenses were \$4.6 million for the year ended December 31, 2014, an increase of \$1.9 million compared to the year ended December 31, 2013. The increase was primarily due to a \$1.0 million increase in outside professional services, which consisted of mostly legal fees, related to the planned listing of our ordinary shares on the Oslo exchange, general corporate matters, including market analysis, communications and investor relations efforts, as well an increase in other legal and accounting costs. We discontinued our planned listing on the Oslo exchange in 2014. Compensation and related personnel costs increased by \$0.6 million for the year ended December 31, 2014 as compared to the year ended December 31, 2013, due to increased hiring of administrative personnel. Travel and other general and administrative costs increased by \$0.3 million for the year ended December 31, 2014 as compared to the year ended December 31, 2013 primarily as a result of the hiring of additional personnel.

Other Income (Expense), Net

The following table summarizes our other income (expense), net, during the years ended December 31, 2013 and 2014:

	<u>Year Ended December 31,</u>		<u>Change</u>
	<u>2013</u>	<u>2014</u>	<u>\$</u>
	(in thousands)		
Foreign exchange loss	\$(570)	\$(204)	\$366
Other income, net	282	486	204
Total other income (expense), net	<u>\$(288)</u>	<u>\$ 282</u>	<u>\$570</u>

Other income (expense), net, changed from expense of \$0.3 million in 2013 to income of \$0.3 million in 2014. The change was primarily due to the strength of the U.S. dollar and the positive impact on the revaluation of our U.S. dollar based currency derivative contracts and interest income earned on deposits, partially offset by foreign exchange loss.

Income Tax Benefit

We recorded income tax benefit of \$0.1 million and \$0.5 million for the years ended December 31, 2013 and 2014, respectively, due to the generation of U.S. state and federal net operating loss carry forwards and federal tax credit carry forwards. The income tax benefit for U.S. state and federal net operating loss carry forwards and the federal tax credit carry forwards has been recognized to the extent it is supported by the deferred tax liabilities recorded in connection with the acquisition of BioPancreate.

Net Loss Attributable to Non-Controlling Interest

Until October 2013, we held 49% of the equity interests in BioPancreate Inc., which was developing biological therapeutics, including BP-2001 for the treatment of diabetes. For 2013, we consolidated BioPancreate's financial results with our own because we controlled BioPancreate, but we attributed a portion of our consolidated net loss in the amount of \$92,000 to the other, non-controlling equity holders of BioPancreate. We acquired the remaining equity interests in BioPancreate in October 2013 and January 2014. Accordingly, in 2014 there was no attribution of any of our net loss to a non-controlling interest.

Liquidity and Capital Resources

We do not expect to generate significant revenue from product sales unless and until we obtain regulatory approval of and commercialize our current or any future product candidates. We anticipate that we will continue to generate losses for the foreseeable future, and we expect the losses to increase as we continue the development of and seek regulatory approvals for our product candidates and begin to commercialize any approved products. We are subject to all of the risks applicable to the development of new products, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may harm our business. Upon the closing of this offering, we expect to incur additional costs associated with operating as a public company and we anticipate that we will need substantial additional funding in connection with our continuing operations.

Our operations have been financed primarily by net proceeds from the issuance of ordinary shares. Our primary uses of capital are, and we expect will continue to be, third-party expenses associated with the planning and conduct of clinical trials, costs of process development services and manufacturing of our product candidates, and compensation-related expenses. We also expect our cash

needs to increase to fund potential in-licenses, acquisitions or similar transactions as we pursue our strategy.

Cash used to fund operating expenses is affected by the timing of when we pay expenses, as reflected in the change in our outstanding accounts payable and accrued expenses. We believe that our existing cash and cash equivalents, which include net proceeds from the private placements completed in 2015, together with the proceeds we expect to receive from this offering, will be sufficient to meet our projected operating requirements through at least the next 12 months.

Our future funding requirements will depend on many factors, including the following:

- the scope, rate of progress, results and cost of our preclinical studies and clinical trials and other related activities;
- the cost of formulation, development, manufacturing of clinical supplies and establishing commercial supplies of our product candidates and any other product candidates that we may develop, in-license or acquire;
- the cost, timing and outcomes of pursuing regulatory approvals;
- the cost and timing of establishing administrative, sales, marketing and distribution capabilities;
- the terms and timing of any collaborative, licensing and other arrangements that we may establish, including any required milestone and royalty payments thereunder; and
- the emergence of competing technologies and their achieving commercial success before we do or other adverse market developments.

We expect to continue to incur losses. Our ability to achieve and maintain profitability is dependent upon the successful development, regulatory approval and commercialization of our product candidates and achieving a level of revenues adequate to support our cost structure. We may never achieve profitability, and unless and until we do, we will continue to need to raise additional capital. If we need to raise additional capital to fund our operations and complete our ongoing and planned clinical trials, funding may not be available to us on acceptable terms, or at all.

We plan to continue to fund our operations and capital funding needs through equity or debt financing. The sale of additional equity would result in additional dilution to our shareholders. The incurrence of debt financing would result in debt service obligations and the instruments governing such debt could provide for operating and financing covenants that would restrict our operations. If we are not able to secure adequate additional funding, we may be forced to make reductions in spending, extend payment terms with suppliers, liquidate assets where possible or suspend or curtail planned programs. In addition, lack of funding would limit any strategic initiatives to in-license or acquire additional product candidates or programs.

Cash Flows

Six Months Ended June 30, 2014 Compared to Six Months Ended June 30, 2015

	Six Months Ended June 30,	
	2014	2015
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	\$(3,724)	\$(15,665)
Investing activities	(5)	(3,193)
Financing activities	—	58,298
	(3,729)	39,440
Effect of exchange rate changes on cash and cash equivalents	(10)	(685)
Net (decrease) increase in cash and cash equivalents	\$(3,739)	\$ 38,755

Operating Activities

Net cash used in operating activities was \$15.7 million for the six months ended June 30, 2015, compared to \$3.7 million for the six months ended June 30, 2014. The increase in net cash used was primarily due to increased operating expenses due to additional headcount, increase in professional fees related to this offering, redomicile to Ireland, business development activities, increased clinical trial activities and other research activities.

Investing Activities

Net cash used in investing activities was \$3.2 million due to the Asperio asset purchase and the result of the purchase of office equipment and furniture.

Financing Activities

Net cash provided by financing activities of \$58.3 million for the six months ended June 30, 2015 was the result of private placement equity financings.

Year Ended December 31, 2013 Compared to Year Ended December 31, 2014

	Year Ended December 31,	
	2013	2014
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	\$(3,475)	\$(9,504)
Investing activities	(2)	(24)
Financing activities	14,924	10,193
	11,447	665
Effect of exchange rate changes on cash and cash equivalents	(455)	70
Net increase in cash and cash equivalents	\$10,992	\$ 735

Operating Activities

Net cash used in operating activities was \$9.5 million for the year ended December 31, 2014, compared to \$3.5 million for the year ended December 31, 2013. The increase in net cash used was primarily due to increased operating expenses due to additional headcount, increased clinical trial activities and other research activities.

Investing Activities

Net cash used in investing activities for 2013 and 2014 was the result of the purchase of office equipment and furniture.

Financing Activities

Net cash provided by financing activities was \$10.2 million for the year ended December 31, 2014, compared to \$14.9 million for the year ended December 31, 2013, which in both years was the result of private placement equity financings.

Contractual Obligations and Other Commitments

The following table summarizes our future minimum commitments at June 30, 2015:

	Payments due by period				Total
	Less than 1 year	1 to 3 years	3 to 5 years	More than 5 years	
	(in thousands)				
Operating leases	<u>\$175</u>	<u>\$762</u>	<u>\$551</u>	<u>\$—</u>	<u>\$1,488</u>
Total contractual obligations	<u>\$175</u>	<u>\$762</u>	<u>\$551</u>	<u>\$—</u>	<u>\$1,488</u>

The above table also excludes potential payments due to two individuals who previously served as officers of our company pursuant to consulting agreements. In connection with those agreements, each individual is entitled to a payment in the event of the sale or license by us prior to December 31, 2016 of BioPancreate or major assets derived from the BioPancreate technology. The payment amounts are based on a percentage of the acquisition price or up-front license fee, as applicable. The maximum amount payment per individual in the event of a sale or license is \$2.5 million or \$1.25 million, respectively. Each individual is entitled to such payments even though each is no longer serving in their respective officer roles.

We enter into agreements in the normal course of business with CROs for clinical trials and with vendors for preclinical studies and other services and products for operating purposes, which are cancelable at any time by us, generally upon 30 days prior written notice. Future payment obligations under these agreements are not included in this table of contractual obligations.

We are obligated to make future payments to third parties under in-license agreements, including sublicense fees, royalties and payments that become due and payable upon the achievement of development and commercialization milestones. As the amount and timing of sublicense fees and the achievement and timing of these milestones are not probable and estimable, such commitments have not been included on our consolidated balance sheets or in the contractual obligations table above. See footnote 6 of the consolidated financial statements for a description of our license agreements.

Off-Balance Sheet Arrangements

We do not have variable interests in variable interest entities or any off-balance sheet arrangements.

Quantitative and Qualitative Disclosures About Market Risk

At June 30, 2015, we had cash and cash equivalents of \$54.4 million, which consisted primarily of bank deposits in the United States, Sweden and Norway. Cash deposits in Sweden and Norway were \$6.9 million as of June 30, 2015 and are subject to local banking laws and may bear higher or lower risk than cash deposited in the United States. As part of our cash and investment management processes, we perform periodic evaluations of the credit standing of the financial institutions with which we deposit our cash or purchase cash equivalents, and we have not sustained any credit losses from instruments held at these financial institutions.

Recent Accounting Pronouncements

During the quarter ended September 30, 2014, the FASB issued *ASU No. 2014-15, Presentation of Financial Statements—Going Concern (ASU No. 2014-15)*. The new guidance addresses management's responsibility to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern and to provide related footnote disclosures. Management's evaluation should be based on relevant conditions and events that are known and reasonably knowable at the date that the financial statements are issued. The standard will be effective for the first interim period within annual reporting periods beginning after December 15, 2016. Early adoption is permitted, but we have not elected to do so. We do not expect the adoption of ASU 2014-15 to have an impact on our financial position or results of operations.

In April 2015, the FASB issued ASU No. 2015-05, *Customer's Accounting For Fees Paid In A Cloud Computing Arrangement*, which provides guidance for a customer's accounting for cloud computing costs. Under ASU 2015-05, if a software cloud computing arrangement contains a software license, customers should account for the license element of the arrangement in a manner consistent with the acquisition of other software licenses. If the arrangement does not contain a software license, customers should account for the arrangement as a service contract. This standard may be applied either prospectively to all arrangements entered into or materially modified after the effective date, or retrospectively. ASU 2015-05 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2015, and early adoption is permitted. The Company is currently evaluating the impact of the adoption of this standard on its consolidated financial statements.

BUSINESS

Overview

We are a biopharmaceutical company focused on the development, in-licensing, acquisition and eventual commercialization of multiple complementary products and product candidates within franchises that target rare diseases. Our primary focus has been to build our rare endocrine franchise, which includes product candidates for the treatment of endogenous Cushing's syndrome and acromegaly, two rare diseases with a high unmet need for innovative treatment options. Given the well-identified and concentrated prescriber base addressing our target markets, we believe we can use a small, focused sales force to effectively market our products, if approved, in the United States, the European Union and other key global markets. We believe that our ability to execute on this strategy is enhanced by the significant clinical development and commercial experience of key members of our management team. We also intend to identify and in-license or acquire products or product candidates that would be complementary to our existing rare endocrine franchise or that would form the basis for new rare disease franchises. We believe this approach will enable us to maximize our commercial potential by further leveraging our existing resources and expertise.

Our rare endocrine franchise includes the following product candidates:

- *COR-003 (levoketoconazole), a cortisol synthesis inhibitor, in Phase 3 clinical development for the treatment of endogenous Cushing's syndrome.* Endogenous Cushing's syndrome is a rare endocrine disorder characterized by sustained elevated cortisol levels that most commonly result from a benign tumor of the pituitary gland. We believe that COR-003 has the potential to become the new standard of care for the drug therapy of endogenous Cushing's syndrome. COR-003 may provide a favorable efficacy, safety and tolerability profile compared to current drug therapies, including ketoconazole, the most commonly used drug therapy for endogenous Cushing's syndrome. COR-003 has been granted orphan drug designation by the U.S. Food and Drug Administration, or the FDA, and the European Medicines Agency, or the EMA. We are developing COR-003, a single enantiomer of ketoconazole, as a new chemical entity, or NCE, under the FDA 505(b)(2) regulatory pathway, and intend to reference the FDA's prior conclusions of safety and effectiveness for ketoconazole. Molecules of ketoconazole occur in two forms, which are mirror images of each other. These mirror image pairs are referred to as enantiomers. Single enantiomer drugs may offer safety and efficacy advantages because one of the enantiomer versions can have safety issues or be less effective in treatment of the disorder or disease. The 505(b)(2) regulatory approval pathway allows companies developing drug products to rely in part on FDA conclusions of safety and effectiveness from studies that were not conducted by or for the applicant. Because approval can rest in part on data already accepted by the FDA or otherwise publicly available, an abbreviated and reduced development program may be possible. We are currently conducting a pivotal Phase 3 clinical trial for COR-003 and expect to report top-line data from this trial in the first half of 2017 and file applications for regulatory approval in the second half of 2017.
- *COR-004, a second-generation antisense oligonucleotide, in Phase 2 clinical development for the treatment of acromegaly.* Acromegaly is a rare endocrine disorder that most commonly results from a benign tumor of the pituitary gland, leading to excess production of growth hormone, or GH, and insulin-like growth factor 1, or IGF-1, a key regulator of growth and metabolism. COR-004 has a novel mechanism of action targeting human GH receptor messenger RNA, or GHR mRNA, a molecule that is necessary for the synthesis of GHR protein. Currently, somatostatin analogs, or SSAs, are the most commonly used drug therapy for the treatment of patients with acromegaly. Up to one-half of treated patients do not adequately respond to SSAs and need alternative or adjunctive drug therapies. The novel mechanism of action of

COR-004 may result in a differentiated safety and efficacy profile as compared to pegvisomant, the most common drug therapy used as an alternative to or in combination with SSAs. In contrast to daily administration of pegvisomant, we intend to develop COR-004 for once- or twice-weekly administration, potentially leading to improved patient compliance. In addition, we plan to develop COR-004 to be packaged in pre-filled syringes, eliminating the need for reconstitution, in contrast to most other drug therapies for acromegaly. We intend to seek orphan drug designation for COR-004 from the FDA and the EMA. Following a planned pre-Investigational New Drug, or IND, consultation with the FDA in the second half of 2015, we intend to file an IND for COR-004 in the United States and begin a multinational development program to support regulatory approval in the United States and subsequently the European Union.

- *COR-005, a novel SSA, in Phase 2 clinical development for the treatment of acromegaly.* Based on the differentiated activation pattern of COR-005 to somatostatin receptor subtypes, or SSTRs, and preclinical and clinical data, we believe that COR-005 may offer an improved efficacy and safety profile relative to existing drug therapies for acromegaly. COR-005 has been granted orphan drug designation by the FDA and the EMA. Following a planned consultation with the FDA and EMA in the first half of 2016, we intend to file an IND for COR-005 in the United States and begin a multinational development program to support regulatory approval in the United States and European Union.

Since the introduction of our new management team beginning in August 2014, we have established a rare disease, franchise-based business model focused on expansion through a disciplined in-licensing and acquisition strategy. In pursuit of our growth strategy, we have raised over \$70 million since December 2014 from leading life sciences investors, including RA Capital, New Enterprise Associates, Broadfin Capital, HealthCap, Longwood Capital, TVM Capital and Granite Point Capital. Leveraging this capital and our experience in sourcing, selecting, in-licensing and acquiring product candidates, we were successful in augmenting our rare endocrine franchise by adding COR-004 and COR-005 to our product pipeline. We believe that these clinical product candidates, if successful, will benefit from significant development and commercial synergies with our lead product candidate, COR-003, because both Cushing's disease and acromegaly are typically caused by benign pituitary tumors and are mainly treated by pituitary endocrinologists. Given the concentrated specialty prescriber base for these indications, we plan to create a sales force of approximately 30 representatives in each of the United States and the European Union to market our endocrine franchise product candidates, if approved. In addition, we believe the development of two product candidates with different mechanisms of action to treat acromegaly may potentially enable us to address the broad acromegaly patient population requiring drug therapy.

Our Strategy

Our goal is to transform the lives of patients by building a leading franchise-based, commercially oriented biopharmaceutical company addressing rare diseases with significant unmet medical needs. We are focused on developing, in-licensing, acquiring and eventually commercializing products and product candidates that target rare diseases across several complementary therapeutic areas.

To achieve our goal, we are pursuing the following strategies:

- ***Focus on rare diseases.*** We are developing treatments for rare diseases, initially endogenous Cushing's syndrome and acromegaly. Rare diseases typically have a high unmet need for innovative treatment options. Drug development for the treatment of rare diseases often requires smaller clinical trials and has the potential for accelerated regulatory review. Product candidates focused on rare diseases also often qualify for orphan drug designation,

which in the United States provides for seven years of market exclusivity and in the European Union provides for 10 years of market exclusivity after regulatory approval has been granted. In addition, given the well-identified and concentrated prescriber base addressing our target markets, we believe we can use a small, focused sales force to effectively promote our products in key geographies. We believe these characteristics enable more efficient resource allocation.

- ***Independently commercialize products in the United States and the European Union.*** We intend to independently commercialize our rare disease product candidates, if approved, in the United States and the European Union, and selectively in other key global markets. Given the concentrated specialty prescriber base, we plan to create a sales force of approximately 30 representatives in each of the United States and the European Union to market our rare endocrine disease product candidates, if approved. We believe that our ability to execute on this strategy is enhanced by the significant prior commercial experience of key members of our management team. Prior to joining our company, members of our management team were involved in the launch or commercialization of over 20 pharmaceutical products.
- ***Expand our portfolio through a disciplined in-licensing and acquisition strategy.*** We plan to source new product candidates by in-licensing or acquiring them. Our management team seeks to mitigate the potential risks of this strategy by adhering to our disciplined criteria of focusing on in-licensing or acquisition opportunities of products that are already commercially available or that have human clinical data that we believe suggest a high probability of success for development progression and an attractive potential return on investment. As a result of our management team's experience in sourcing, selecting, in-licensing and acquiring product candidates, we were successful in augmenting our rare endocrine franchise by adding COR-004 and COR-005 to our product pipeline.
- ***Utilize a franchise model built on rare disease therapeutic areas.*** We intend to build our company by creating franchises in areas where there is a significant commercial opportunity. We seek to in-license and acquire products and product candidates that target rare diseases in therapeutically aligned franchises. We believe that complementary products and product candidates will allow us to significantly leverage our expertise as well as our development and commercial infrastructure. For example, our product candidates for the treatment of endogenous Cushing's syndrome and acromegaly, if approved, will serve as the basis for our rare endocrine franchise.
- ***Expand indications of products and product candidates within our franchises.*** In addition to identifying products and product candidates that can form the basis of new rare disease franchises, we also intend to leverage opportunities to develop potential products and product candidates for additional indications within their respective therapeutic franchises. We believe that this approach will enable us to maximize our commercial potential by further leveraging our existing resources and expertise.

Our Product Candidate Pipeline

The following table illustrates our product candidates by stage:

	Target Disease	Preclinical	Phase 1	Phase 2	Phase 3	Comments
Our Rare Endocrine Franchise						
COR-003 (levoketoconazole)	Endogenous Cushing's syndrome (FDA and EMA orphan drug designation)					Ongoing Phase 3 pivotal clinical trial* Top-line data in 1H 2017 NDA/MAA filing in 2H 2017
COR-004 (second-generation antisense oligonucleotide targeting GHR)	Acromegaly (In-licensed May 2015)					Ongoing Ex-U.S. Phase 2 clinical trial. Pre-IND meeting with FDA in 2H 2015 Plan to file for orphan drug designation
COR-005** (somatostatin analog)	Acromegaly (Acquired May 2015) (FDA and EMA orphan drug designation)					Pre-IND meeting with FDA and Scientific Advice meeting in Europe in 1H 2016
Other Product Candidates						
BP-2001 (gene modified probiotic)	Diabetes Type 1 and 2					IND application planned for 1H 2016

* Prior Phase 2 clinical trials were conducted in diabetes patients.

** COR-005 is also being evaluated for the potential treatment of Cushing's disease and neuroendocrine tumors.

Our Rare Endocrine Franchise

We have three product candidates within our rare endocrine franchise. Our lead product candidate, COR-003, is a cortisol synthesis inhibitor and is a single enantiomer of ketoconazole that we are developing for the treatment of endogenous Cushing's syndrome. We recently in-licensed and acquired two additional clinical-stage product candidates that we are developing for the treatment of acromegaly. COR-004 is a second-generation antisense oligonucleotide and COR-005 is a novel SSA, both of which have the potential to provide new and differentiated treatment options for patients with acromegaly. We believe that these three clinical product candidates, if successful, will benefit from significant development and commercial synergies based on the fact that both endogenous Cushing's syndrome and acromegaly are typically caused by benign pituitary tumors and are mainly treated by pituitary endocrinologists. We believe that we can address the markets for all three of these product candidates by targeting the endocrinologists that are focused on the treatment of rare pituitary disorders.

Overview of COR-003—Phase 3 Product Candidate for the Treatment of Endogenous Cushing's Syndrome

We are developing COR-003 for the treatment of endogenous Cushing's syndrome, a rare endocrine disorder characterized by excessive cortisol levels. In endogenous Cushing's syndrome, elevated circulating cortisol levels give rise to a severe disease with variable clinical symptoms, including weight gain, characteristic changes in fat distribution, diabetes, hypertension, osteoporosis, muscle loss and depression. The active pharmaceutical ingredient in COR-003, levoketoconazole (single enantiomer of ketoconazole, 2S,4R-ketoconazole), exerts its effect by blocking the synthesis of cortisol leading to the reduction and normalization of cortisol levels. COR-003 has been granted orphan drug designation

by the FDA and the EMA. We are currently conducting a pivotal Phase 3 clinical trial for COR-003 and expect to report top line data from this trial in the first half of 2017 and file applications for regulatory approval in the second half of 2017.

Ketoconazole, used off-label in the United States, is the most frequently prescribed and efficacious drug therapy for endogenous Cushing's syndrome. It is used to reduce cortisol levels and ameliorate significant comorbidities. Molecules of ketoconazole occur in two forms, which are mirror images of each other. These mirror image pairs are referred to as enantiomers. Manufactured ketoconazole contains a 1:1 mixture of the two enantiomers, 2R,4S-ketoconazole and 2S,4R-ketoconazole, and is therefore referred to as a racemic mixture. COR-003 is a single-enantiomer drug, a pure form of one of the two enantiomers (2S,4R-ketoconazole) of racemic ketoconazole. Single-enantiomer drugs may offer safety and efficacy advantages because one of the enantiomer versions in the racemic mixture can have safety issues or be less effective in treatment of the disorder or disease. COR-003, like ketoconazole, is a cortisol synthesis inhibitor that inhibits the cortisol synthesis pathway at three points. In light of the shared mechanism of action with ketoconazole and the data from Phase 2 clinical trials, which were conducted in diabetes patients, we believe COR-003 may have a similar beneficial impact on the reduction of significant comorbidities of endogenous Cushing's syndrome, including those associated with cardiovascular-related mortality risk, such as diabetes, weight, hypertension and elevation in cholesterol. In addition, based on preclinical and clinical results, we believe that COR-003 may offer an improved safety profile relative to existing approved drug therapies. As a result, we believe that COR-003 has the potential to become the new standard of care for the drug therapy of endogenous Cushing's syndrome.

Overview of Cushing's Syndrome

There are two variants of Cushing's syndrome: exogenous, which is caused by factors outside the body; and endogenous, which is caused by factors within the body. The symptoms for both are the same. The more common form is exogenous Cushing's syndrome, which is often found in people taking cortisol-like medications for long periods of time at high dosages. Cortisol-like medications are often used to treat inflammatory disorders such as asthma and rheumatoid arthritis. Unlike the endogenous variant, this type of Cushing's syndrome is temporary and clinical signs and symptoms subside in part after the patient has finished taking the cortisol-like medication.

Endogenous Cushing's syndrome is a rare endocrine disorder characterized by sustained elevated cortisol levels. Cortisol is a hormone produced in the adrenal gland and is naturally secreted as an end product of the activity of the hypothalamic-pituitary-adrenal axis, a major part of the endocrine system. Corticotropin-releasing-hormone, or CRH, is secreted from the hypothalamus and stimulates the secretion and release of adrenocorticotropin, or ACTH, from the pituitary gland, which in turn stimulates cortisol secretion from the adrenal gland. Cortisol itself exerts negative feedback control on both CRH in the hypothalamus and ACTH in the pituitary gland, thereby reducing CRH and ACTH secretion and keeping cortisol levels in a normal range.

The most common form of endogenous Cushing's syndrome is Cushing's disease, which is typically caused by a benign pituitary tumor that secretes ACTH. Cushing's disease represents approximately 70% to 80% of patients with endogenous Cushing's syndrome. Other less frequent causes of endogenous Cushing's syndrome include extrapituitary tumors producing ACTH, or ectopic ACTH syndrome. The source of ectopic ACTH secretion is most often small-cell carcinoma of the lung or bronchial carcinoid tumors, but can also arise with almost any endocrine tumor from many different organs. In a smaller number of cases, approximately 20%, endogenous Cushing's syndrome can be ACTH-independent, resulting from excess secretion of cortisol by unilateral adrenocortical tumors, either benign or malignant, or by non-malignant enlargement of the adrenal glands.

In patients with endogenous Cushing's syndrome, the normal feedback mechanism of the hypothalamic-pituitary-adrenal axis for cortisol secretion is disrupted as a result of a tumor secreting ACTH, CRH or cortisol. This causes chronic exposure to high circulating cortisol levels that give rise to

the clinical state of Cushing's syndrome. The most common signs and symptoms include: weight gain, especially in the upper body; rounded face and extra fat on the upper back and above the collarbones; high blood sugar or diabetes; high blood pressure or hypertension; thin bones or osteoporosis; muscle loss and weakness; thin, fragile skin that bruises easily; purple-red stretch marks, usually over the abdomen and under the arms; depression and difficulty thinking clearly; too much facial hair in women; irregular or absent menstrual periods and infertility; reduced sex drive; and in children, poor height growth and obesity.

An estimated 25,000 patients in the United States and 40,000 patients in Europe are currently diagnosed with endogenous Cushing's syndrome. Patients are most commonly adults aged 20 to 50 and five times more women than men are affected. However, endogenous Cushing's syndrome is believed to be underdiagnosed due to lack of disease recognition by the treating physician, which often leads to a delay in diagnosis of six years on average. Endogenous Cushing's syndrome patients are believed to have a mortality risk up to five times that of the general population, with cardiovascular disease, venous thrombosis and infections being the primary causes of death.

Current Treatment Landscape and Limitations on Current Treatment Options

Treatment of endogenous Cushing's syndrome varies depending on the cause of the disease. For patients with Cushing's disease, a subset representing the majority of patients with endogenous Cushing's syndrome, initial treatment is almost always the attempted surgical removal of the tumor. In anticipation of surgery and when surgery is not effective or not feasible, drug or radiation therapy, or both, is used to suppress excessive cortisol production and the accompanying clinical symptoms.

A typical approach of drug therapy is to inhibit cortisol biosynthesis through the oral administration of an inhibitor of enzymes of adrenal cortisol synthesis. Ketoconazole is the most widely used drug therapy for endogenous Cushing's syndrome, but it is not approved for this indication in the United States. The percentage of endogenous Cushing's syndrome patients who achieve normalized levels of cortisol, assessed by measuring urinary free cortisol, or UFC, with ketoconazole has been reported from retrospective uncontrolled studies to vary between 33% and 100%. Data from one retrospective study of 200 patients in 14 French centers solely treated with ketoconazole off label for active Cushing's syndrome between 1995 and 2012 showed ketoconazole controlled cortisol secretion in approximately 50% of patients and improved clinical symptoms. Also, beneficial effects on clinical symptoms and signs that drive the morbidity and mortality of endogenous Cushing's syndrome have been reported, such as the reduction in high blood pressure, improvement of diabetes, and normalization of hypokalemia, or low potassium blood levels. However, a significant proportion of patients treated with ketoconazole experience tolerability issues and, in some cases, hepatotoxicity. As a result of the hepatotoxicity risk, including in patients without existing liver disease, the FDA has issued a black box warning concerning the use of ketoconazole to treat fungal infections, its approved indication. Although the elevations in liver function tests associated with ketoconazole are generally modest in nature, in rare cases, severe hepatotoxicity may occur (one in every 10,000 to 15,000 patients). In extremely rare cases, this adverse reaction may be irreversible and result in death or require liver transplantation. In Europe, ketoconazole was taken off the market for the treatment of fungal infections due to similar safety concerns, but was recently approved for the treatment of endogenous Cushing's syndrome without any clinical trials based on significant unmet need, well-established use in medical practice and documentation in scientific literature.

An alternative approach to treatment is the use of drugs that target pituitary tumors that produce ACTH. This approach is only useful in the subset of patients whose endogenous Cushing's syndrome is caused by a pituitary tumor, or Cushing's disease. Among Cushing's disease patients, the dopamine agonist cabergoline, which is not approved for use in Cushing's disease, has been shown to achieve normalization of UFC levels in about 30% of patients. The SSA pasireotide, which is marketed as Signifor for the treatment of Cushing's disease, has shown normalization of UFC levels in 15% of

patients at a 600 µg dose and in 26% of patients at a 900 µg dose. Certain SSAs, including Signifor, are known to have undesirable side effects on glucose metabolism. Forty percent of patients with Cushing’s disease treated with Signifor in its Phase 3 clinical trial reported the occurrence of hyperglycemia-related adverse events.

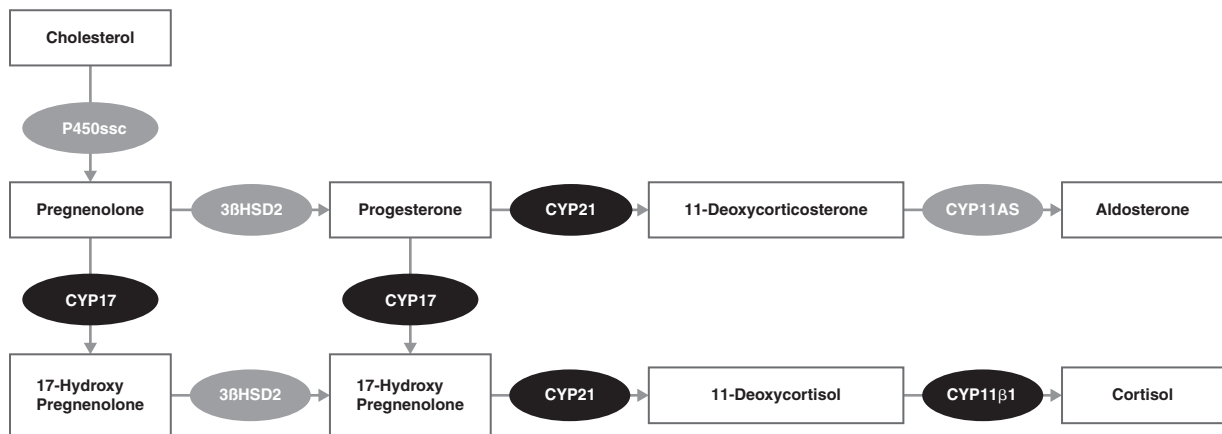
Another alternative, Korlym, or mifepristone, works by inhibiting the action of cortisol at the receptor level, but does not lower cortisol levels. As a result of this mechanism of action, it is not possible to monitor response by measuring UFC levels, which is the standard for physicians who treat endogenous Cushing’s syndrome. Korlym has been approved in the United States to control hyperglycemia secondary to hypercortisolism in patients with endogenous Cushing’s syndrome. Korlym is contra-indicated in pregnant women and in women with a history of unexplained vaginal bleeding, as its side effects include termination of pregnancy, endometrial thickening and vaginal bleeding.

We believe that efficacy limitations and safety concerns with currently available drug therapies for endogenous Cushing’s syndrome have resulted in a significant unmet medical need among endogenous Cushing’s syndrome patients for alternative drug therapies. In a survey we commissioned in 2014 of 89 U.S. physicians treating patients with Cushing’s syndrome, when asked, “Of your patients on medication to manage cortisol levels, what percentage are well controlled?”, the physicians estimated that only approximately 37% of such patients were well controlled. Thus, we believe that our potential addressable market for COR-003 would be the one-third of all diagnosed endogenous Cushing’s syndrome patients that at any one point in time are eligible for drug therapy, a figure that represents patients anticipating surgery, for whom surgery or radiation is not feasible, is contraindicated or has been unsuccessful. This unmet need may also be impacted by what we believe to be the current lack of disease awareness among physicians and patients, resulting in a low rate of diagnosis.

Our Solution—COR-003

We believe that COR-003 has the potential to become the new standard of care for the drug therapy of endogenous Cushing’s syndrome because it may provide a favorable efficacy, safety and tolerability profile compared to current drug therapies, including ketoconazole, the most commonly used drug therapy for the treatment of endogenous Cushing’s syndrome. We believe COR-003, based on its similar mechanism of action to that of ketoconazole, may improve UFC levels, in contrast to Korlym, and may have an anti-diabetic effect, in contrast to Signifor. In addition, we believe COR-003 may have an improved safety profile, compared with that of ketoconazole.

COR-003, like ketoconazole, is a cortisol synthesis inhibitor that inhibits the cortisol synthesis pathway at three points. The following graphic illustrates the cortisol synthesis pathway:



■ Enzymes inhibited by COR-003

Our preclinical and pharmacokinetic data suggest that COR-003 may have an efficacy profile at least as favorable as ketoconazole and may have less risk for impairing liver function:

- In *in vitro* studies, COR-003 was found to have higher potency than ketoconazole and the mirror-image single enantiomer, 2R,4S-ketoconazole, in inhibiting the key enzymes in cortisol synthesis (CYP11 β 1, CYP17). Thus, we believe COR-003 may have the same or higher efficacy compared to ketoconazole at lower doses, which may in turn reduce the drug load for the liver and may contribute to increased safety and tolerability.
- The pharmacokinetics of the enantiomers also suggest potentially greater safety of COR-003 relative to ketoconazole. Enantiomers in racemic ketoconazole are present in equal proportions, but in a Phase 1 clinical trial in healthy subjects, it was observed that following administration of ketoconazole, blood concentrations of the single enantiomer, 2S,4R-ketoconazole (*i.e.*, COR-003) exceeded those of the other single enantiomer, 2R,4S-ketoconazole, by approximately three times. This may suggest that the single enantiomer, 2R,4S-ketoconazole, is extracted by the liver to a greater extent than the other single enantiomer, 2S,4R-ketoconazole (*i.e.*, COR-003), and may therefore contribute more than COR-003 to the observed liver toxicity of racemic ketoconazole.
- Compared with racemic ketoconazole, it was observed in *in vitro* studies that COR-003 is less potent than the other enantiomer in inhibiting the activity of CYP7A. CYP7A is the first and rate-limiting enzyme for production of bile acids in the liver. While a role of CYP7A in liver injury is not established, this finding suggests a possible differential effect of the ketoconazole enantiomers on metabolic and detoxifying enzymes in the liver contributing to potentially reduced hepatotoxicity of COR-003.

Previously, COR-003 was studied for the treatment of type 2 diabetes. DiObex, our licensee from 2004 to 2008, initiated five clinical trials to investigate the use of COR-003 for type 2 diabetes. In December 2005, prior to the initiation of the first clinical trial by DiObex, the FDA placed a clinical hold relating to a safety concern for use of a dosage above 600 mg/day. DiObex modified the clinical trial protocol to limit the highest dose to 600 mg/day, and the clinical hold was lifted by the FDA in February 2006. In a Phase 2 clinical trial of type 2 diabetes patients, COR-003 demonstrated a significant dose response in the reduction in mean levels of C-reactive protein, or CRP, whereas for ketoconazole, an increase in CRP was found. Higher levels of CRP indicate the presence of inflammation, including in the liver and the cardiovascular system. Thus, we believe that COR-003 may be associated with a decrease in inflammatory processes compared to racemic ketoconazole. COR-003, with the same mechanism of action as ketoconazole, may also have, like ketoconazole, beneficial effects on cardiovascular risk factors, which are the leading cause of mortality for endogenous Cushing's syndrome, including weight loss, reduction in blood sugar, lowering of cholesterol and reduction in blood pressure.

Clinical and Preclinical Development of COR-003

Phase 3 Clinical Trial

We are conducting a pivotal Phase 3 clinical trial of COR-003 investigating the safety and efficacy of COR-003 in subjects with endogenous Cushing's syndrome and expect to report top-line data from this trial in the first half of 2017. This clinical trial is being conducted pursuant to an IND we filed in April 2013. We intend to file applications for regulatory approval for COR-003 in the second half of 2017 for the treatment of patients with endogenous Cushing's syndrome for whom surgery is not feasible, is contraindicated or has been unsuccessful. COR-003 is an NCE for which we intend to pursue regulatory approval under the FDA's 505(b)(2) regulations, referencing the FDA's conclusions of safety and effectiveness in the new drug application, or NDA, for ketoconazole. The 505(b)(2) regulatory approval pathway was established to allow companies developing drug products to obtain

approval by relying in part on agency conclusions of safety and effectiveness from studies that were not conducted by or for the applicant. Because approval can rest in part on data already accepted by the FDA or otherwise available in the public domain, an abbreviated and reduced development program may be required, thus mitigating costs and shortening development time. The FDA has acknowledged that no additional preclinical investigations will be required for COR-003. The EMA's Committee for Medical Products for Human Use, or CHMP, has requested a study of reproductive toxicity that will be completed prior to filing in Europe.

Several elements of the clinical trial design have been informed by the clinical development pathway of currently approved drug therapies in the United States and the European Union. Additionally, we incorporated advice from the CHMP and FDA into the design of the clinical trial. In discussions we had with the FDA, they recommended, but did not require, a control group. We are using an open-label, single-arm design because in the past the FDA has deemed that the concurrent use of a placebo control as monotherapy is unethical for the treatment of endogenous Cushing's syndrome. In addition, based on our analysis and feedback from experts whom we have consulted, we concluded that it was not practical to use any approved drug to serve as an active control due to the unsuitable mode of action, route of administration and side effect profile of available approved therapies. Studies lacking an active control group are more likely to be subject to unanticipated variability in study results that can potentially lead to flawed conclusions because they do not allow for discrimination of patient outcomes. As a result, even if we achieve the clinical trial's endpoints, the FDA or other regulatory authorities could view our study results as potentially biased and may ultimately require that we conduct a randomized, controlled clinical trial of COR-003 in order to obtain approval for commercialization.

If we can (1) demonstrate consistent and significant clinical benefit by meeting the primary endpoint of the trial, specifically the responder rate measured as normalization of UFC levels and (2) show consistent improvement of objectively quantifiable biomarkers of endogenous Cushing's syndrome comorbidities, such as blood glucose, blood lipids, blood pressure and weight, and improvement of other clinical signs and symptoms of endogenous Cushing's syndrome, we believe this would be regarded by regulators as adequate proof of efficacy in this rare disease with a high unmet medical need.

We are conducting this clinical trial in up to 80 clinical sites in approximately 19 countries, including in the United States, Canada, the European Union and the Middle East. We enrolled our first patient in the clinical trial in August 2014. Our U.S. IND for COR-003 for the treatment of endogenous Cushing's syndrome took effect in May 2013. We plan to recruit 90 patients and collect safety and efficacy data over a treatment period of at least one year. Because our Phase 3 clinical trial will collect safety data for only 90 patients, we currently expect that we would be required by the FDA and the EMA to collect additional safety data post-approval. If we are able to confirm a favorable safety profile of COR-003 in clinical use, we plan to discuss differentiated safety and tolerability labeling from ketoconazole with regulatory authorities.

Our Phase 3 clinical trial is being conducted, after an appropriate washout period, if required, in three phases:

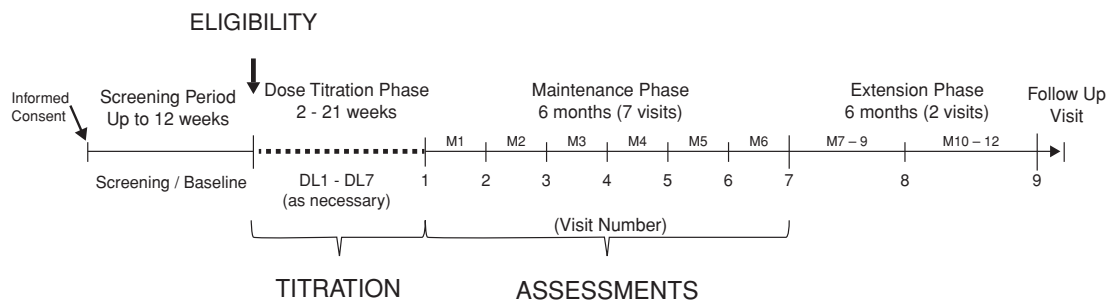
- a dose titration phase that is two weeks to 21 weeks in duration and has up to seven dose levels, or DLs;
- a maintenance phase that is six months in duration; and
- an extension phase that is six months in duration.

During the dose titration phase, patients will start at 150 mg twice daily dosing (300 mg total daily dose) and titrate in 150 mg increments up to a maximum 600 mg twice daily dosing (1,200 mg total daily dose). Following the dose titration phase, once the therapeutic dose has been reached, the

patient will enter the maintenance phase, during which the dose will be fixed and cannot be changed other than for safety reasons. At the end of the six month maintenance phase, UFC levels will be measured and the responder rate, which is the primary endpoint of the clinical trial, will be determined. Patients who have completed the maintenance phase may enter the extension phase, which we expect will provide additional safety and efficacy data. Throughout the entire clinical trial, various measurements for safety and efficacy will be taken.

- The primary endpoint of the clinical trial is the proportion of subjects with response to COR-003, defined as a reduction in mean 24-hour UFC levels to levels that are equal to or less than the upper level of normal range following six months of treatment in the maintenance phase without a dose increase.
- Key secondary endpoints will include the number of patients with at least a 50% decrease in UFC levels, as well as changes in blood sugar, blood pressure, cholesterol and weight compared to baseline, and effects on clinical signs and symptoms of endogenous Cushing's syndrome, quality of life measures obtained from the endogenous Cushing's syndrome quality of life questionnaire and the severity of depression obtained from the Beck's Depression Inventory II.
- The clinical trial is also designed to investigate the pharmacokinetics of COR-003 in patients with endogenous Cushing's syndrome.

Below is a diagram of our clinical trial design:



Clinical Trials in Type 2 Diabetes

Historically, COR-003 was studied as a treatment for type 2 diabetes. An IND was filed in 2005 for investigation of the use of COR-003 in diabetes. DiObex, our licensee at the time, initiated five clinical trials to investigate the use of COR-003 for type 2 diabetes. A total of 159 subjects were dosed in these clinical trials, including 41 healthy subjects during Phase 1 clinical trials, and 118 in patients with type 2 diabetes during Phase 2 clinical trials. Doses of COR-003 were administered over the range of 200 mg to 600 mg once a day, or QD, and 400 mg twice a day, or BID, for a single patient for up to 14 days, and 150 mg to 450 mg QD for up to four months.

The pharmacokinetics of COR-003 were studied in patients with type 2 diabetes and in normal volunteers in whom the effects of COR-003 on the pharmacokinetics of felodipine, a drug used to treat high blood pressure, and atorvastatin (Lipitor), a drug used to lower cholesterol, were evaluated. In the completed Phase 2 clinical trial, dose dependent reductions from baseline in lipoprotein levels, in the form of low-density lipoprotein, or LDL, and high-density lipoprotein, or HDL, and total cholesterol were observed, but no differences in measures of glycemic control relative to placebo were detected. In 2008, in light of negative safety reports for other diabetes treatments such as Avandia, DiObex made the decision to voluntarily terminate the development of COR-003 for the treatment of diabetes due to the perceived high regulatory and commercial hurdles for its approval and use in type 2 diabetes. Thereafter, the IND was closed and DiObex terminated the two ongoing Phase 2 clinical trials.

DiObex conducted the following five clinical trials with COR-003 in type 2 diabetes pursuant to an IND filed by them in November 2005:

Clinical Trial Number	Clinical Trial Description	Subjects Enrolled	Year and Status	Location	Dose
DIO-501	Phase 1/2a, Trial of COR-003 or Placebo in Patients with Type 2 Diabetes Mellitus	37	2006/2007 Completed. Study report issued.	United States	200-600 mg QD; 400 mg BID
DIO-502	Phase 2b Trial of COR-003 or Placebo in Addition to Metformin and Atorvastatin or Atorvastatin Placebo for Type 2 Diabetes Mellitus	129	2007/2008 Terminated early. Study report issued.	United States, Australia, New Zealand	150-450 mg QD
DIO-503	Phase 2 Open-Label Trial and Pharmacodynamic for 24-Week Study with COR-003 in Combination with Metformin and Atorvastatin in Patients with Type 2 Diabetes Mellitus	3	2007/2008 Terminated early. Study report issued.	United States, Australia, New Zealand	150-450 mg QD
AA34509	Phase 1 Pharmacokinetic Drug Interaction Trial of COR-003 with Felodipine in Healthy Adult Volunteers Under Fasting Conditions	18	2006/2007 Completed. Study report issued.	United States	400 mg QD
AA34510	Phase 1 Pharmacokinetic Drug Interaction Trial of COR-003 and Racemic Ketoconazole with Atorvastatin in Healthy Adult Volunteers Under Fasting Conditions	24	2006/2007 Completed. Study report issued.	United States	400 mg QD

Phase 2 Clinical Trials

DIO-501 Clinical Trial

This clinical trial was a double-blind, placebo-controlled, parallel-group clinical trial conducted in patients aged 18 to 70 with a known diagnosis of type 2 diabetes. A total of 35 patients were treated: 21 with COR-003 (10 at 200 mg QD, six at 400 mg QD, four at 600 mg QD and one at 400 mg BID); eight with ketoconazole (400 mg QD); and six with placebo. Trial drugs were administered for 14 days.

In this clinical trial, the mean 12-hour plasma cortisol area under the concentration-time curve, or AUC, levels were modestly reduced in the COR-003 treatment groups at day 15 compared to baseline, which is consistent with the known mechanism of action of COR-003. However, counter-regulation in diabetic patients with a normal hypothalamic pituitary adrenal axis may have limited the observed cortisol suppression. Similarly, only a small, nonsignificant effect on glycated hemoglobin, or HbA1c, and fasting glucose levels was observed. However, consistent with the known inhibitory effect of ketoconazole on cholesterol synthesis, total cholesterol, LDL, and to a lesser extent HDL levels, but not triglycerides, were significantly decreased in a dose-dependent manner by COR-003. The mean change from baseline in total cholesterol, LDL and HDL at a dose of 400 mg QD was similar to those observed in 400 mg QD ketoconazole and higher in the 600 mg QD COR-003 group. Also, for the COR-003 treatment groups, there was a statistically significant dose response in the reduction in mean levels of CRP on day 15 compared with baseline. This result was statistically significant, with a p-value of 0.027. P-value is a conventional statistical method for measuring the significance of clinical results. Typically, a p-value of 0.05 or less represents statistical significance, meaning that there is a 1-in-20 or less statistical probability that the observed results occurred by chance. In contrast, mean levels of CRP increased in the ketoconazole-treated group and less so in the placebo group. CRP is an indicator of inflammation, including vascular inflammation. The reduction in cholesterol and CRP observed in

patients with type 2 diabetes may indicate a potential beneficial effect of COR-003 on cardiovascular risk factors observed in patients with endogenous Cushing's syndrome.

Plasma AUCs and maximum concentration in blood, or C_{max}, increased in a non-proportional manner over the dose range of 200 mg to 400 mg on days one and 14. Clearance values were similar for the 200 mg and 400 mg doses of COR-003, but significantly decreased at the 600 mg COR-003 dose, on days one and 14.

Administration of COR-003 in this trial in patients with type 2 diabetes was observed to be well-tolerated. Headache and nausea were the most frequently reported adverse events, some of which were considered drug-related. There were no serious adverse events, and no clinically meaningful changes in hematology, blood chemistry and urinalysis were noted in any treatment group. No treatment-related changes in liver function tests, or LFTs, were detected.

DIO-502 and DIO-503 Clinical Trials

This clinical trial was a four-month, double-blind, randomized, placebo-controlled clinical trial of dose-ranging COR-003 with metformin and atorvastatin in 200 patients with type 2 diabetes, consisting of males and females between the ages of 18 and 70. Included patients were on concomitant metformin treatment with a minimum daily dose of 500 mg with an HbA1c level of 7% to 10%. Additionally, all patients were treated with 10 mg atorvastatin to evaluate the effect of COR-003 on lipid profiles given cholesterol-lowering drugs. Thus, patients were randomized into eight separate arms in the clinical trial: placebo or COR-003 at 150 mg; 300 mg; and 450 mg with either atorvastatin 10 mg or atorvastatin placebo.

Clinical trial DIO-503 was an open-label, follow-on extension to DIO-502 to evaluate safety, tolerability and pharmacodynamics after 24 weeks of dosing with COR-003 in combination with metformin, and with and without atorvastatin in subjects with type 2 diabetes.

DiObex terminated these clinical trials prior to completion. At the time of trial termination, a total of 133 patients were enrolled in the DIO-502 and DIO-503 trials, and 129 patients had been treated. Efficacy and pharmacokinetics were not analyzed due to the early termination. The frequency of adverse events reported was generally similar across treatment arms. Diarrhea was the most frequently reported adverse event overall with administration of COR-003. No serious adverse events were reported in the terminated studies.

A safety signal of elevated liver enzymes was identified in 10 of the 129 treated patients in the DIO-502 and DIO-503 trials. Three of the treated patients were withdrawn from the clinical trials as required in the safety monitoring plan. In these three patients, LFT levels returned to normal after study drug was discontinued. In addition, three other patients had modest elevations in LFT levels. While these levels did not require termination by the trial protocol, the investigators elected to terminate these patients from the clinical trial. LFTs in these patients also returned to normal after the study drug was discontinued. Four additional patients required close monitoring per the protocol, and had resolution of their LFT abnormalities while on the study drug. The first case of elevated liver enzymes occurred in a patient who admitted to excessive alcohol consumption. The remaining cases developed over the following three months. An independent external safety review committee recommended continuation of the studies with no modifications.

Due to the design of these clinical trials, the independent data safety monitoring board for the trials stated that it was impossible to interpret which of the two drugs, COR-003 or atorvastatin, was primarily associated with the side effect profile observed in these trials. A more detailed analysis of the liver transaminase elevations in this clinical trial showed that there was no correlation between the dose of COR-003 and abnormal liver transaminases.

Phase 1 Clinical Trials

AA34509 Clinical Trial

This clinical trial was designed primarily to evaluate the effect of COR-003 on the pharmacokinetics of concurrently administered felodipine. Subjects were administered 400 mg of COR-003 or placebo QD for eight days. On the fifth day of the trial, subjects received a single 5 mg dose of felodipine. Beginning on day five, pharmacokinetics of COR-003 were monitored for 24 hours, and pharmacokinetics of felodipine were monitored for 72 hours. The trial was a cross-over trial involving 18 subjects, 16 of whom completed the trial.

AA34510 Clinical Trial

This clinical trial was designed primarily to evaluate the effect of concomitant administration of COR-003 or racemic ketoconazole on the pharmacokinetics of atorvastatin. Subjects were administered 400 mg of COR-003, 400 mg of racemic ketoconazole or placebo daily for seven days. On day five, all subjects received a single 80 mg dose of atorvastatin. After administration of the racemic mixture, ketoconazole, pharmacokinetics of the two single enantiomers 2R,4S-ketoconazole and 2S,4R-ketoconazole, were evaluated for 24 hours on day five using a chiral bioanalytical method. Pharmacokinetics of atorvastatin were evaluated for 60 hours starting at the time of administration on day five. The trial was a cross-over trial involving 24 subjects, all of whom completed the clinical trial.

Key Findings from the Clinical Trials of COR-003

Phase 2 Efficacy and Safety Trials in Diabetic Patients:

- AUCs and Cmax values were approximately 50% higher with COR-003 in comparison with ketoconazole at the same dose of 400 mg. All pharmacokinetic parameters were highly variable, in the sense that they differed in and among patients.
- Following administration of racemic ketoconazole, plasma levels of COR-003 were approximately three times those of the other enantiomer, 2R,4S-ketoconazole. Possible explanations could be reduced absorption or increased uptake and metabolism of COR-003 in the liver compared to the other enantiomer.
- COR-003 produced a decrease in some lipid measures, or blood fat, including reduced total cholesterol, LDL and HDL.
- A significant dose-related effect of COR-003 for reduction of CRP was observed.
- Trends for reductions in 12-hour cortisol, measured by AUC, were found after 14 days of treatment with COR-003 in diabetic patients.
- In the DIO-501 clinical trial, headache and nausea were the most frequently reported adverse events. No treatment related changes in LFTs were detected. In the DIO-502/503 clinical trials, diarrhea was the most frequently reported adverse event.
- LFTs were elevated in the DIO-502/503 clinical trials in 10 out of the 129 patients treated with either the combination of COR-003 and atorvastatin or COR-003 alone, in each case co-administered with metformin. The independent data safety monitoring board for the trial stated that it was impossible to interpret which of the two drugs was primarily associated with the side effect profile observed in the trial.

Phase 1 Drug Interaction Clinical Trials in Normal Volunteers:

- The AUC and the C_{max} of felodipine were 10-fold higher when taken with COR-003 compared with felodipine alone.
- The total exposure of atorvastatin was increased by 50% when administered with COR-003 compared with atorvastatin alone.
- A small, but statistically significant decrease of serum cortisol (AUC zero to six hours) was found for COR-003 compared with placebo and ketoconazole.
- Headache, nausea, dizziness and back pain were reported as the most frequent adverse events across the two studies.
- In the drug interaction study with atorvastatin, two subjects had elevated LFT values. The subjects had received COR-003 plus atorvastatin or ketoconazole plus atorvastatin in the immediately previous study periods in this cross-over study.

Overview of COR-004 and COR-005—Phase 2 Product Candidates for the Treatment of Acromegaly

We are developing COR-004 and COR-005 for the treatment of acromegaly. We in-licensed COR-004 and acquired COR-005 in 2015 as part of our strategy to build our rare endocrine franchise. Acromegaly is a rare endocrine disorder that most commonly results from a benign tumor of the pituitary gland, leading to excess production of GH and IGF-1. The treatment goal is the normalization of IGF-1, which is the main cause of the detrimental clinical signs and symptoms of acromegaly.

COR-004 is a second-generation antisense oligonucleotide in Phase 2 clinical development for the treatment of acromegaly patients who do not adequately respond to SSAs. COR-004, which was discovered by ISIS Pharmaceuticals, has a novel mechanism of action targeting GHR mRNA, a molecule that is necessary for the synthesis of human growth hormone receptor, or GHR, protein. Antisense oligonucleotides work by binding to mRNA, triggering its destruction by enzymes before it can be translated into the protein. COR-004 binds to GHR mRNA, thereby preventing GHR from being expressed on cell surfaces. Absence of GHR leads to reduced concentrations of circulating IGF-1, which is responsible for the disease signs and symptoms in acromegaly. COR-004 recently completed a Phase 2 clinical trial that showed a statistically significant reduction in IGF-1 levels at the twice per week 200 mg dose, and a safety profile comparable to that of other second-generation antisense drugs in late-stage development for other indications. We intend to seek orphan drug designation for COR-004 from the FDA and the EMA. We plan to initiate nonclinical animal studies during 2015 and plan to have a pre-IND meeting with the FDA in the second half of 2015 before filing an IND for COR-004 in the United States, and IND-equivalent filings in other regulatory jurisdictions. We anticipate that at least one pivotal registration clinical trial with at least six months of controlled treatment will be needed to evaluate efficacy, along with at least six additional months of treatment observation to evaluate safety. However, depending on advice from regulatory authorities, we may be required to complete an additional clinical trial prior to initiating our pivotal program.

COR-005 is a novel SSA in Phase 2 clinical development for the treatment of acromegaly patients who have not adequately responded to surgery, or acromegaly patients for whom surgery is not appropriate. SSAs are the most commonly used drug therapy for the treatment of acromegaly and work by binding to specific subtypes of SSTRs that are expressed by the tumor. Binding of SSAs to these SSTRs leads to the beneficial inhibition of GH secretion, but also unwanted inhibition of secretion of other endocrine hormones such as insulin and glucagon in other organs. Based on the differentiated activation pattern of COR-005 to SSTR subtypes and preclinical and clinical data, we believe that it may offer an improved efficacy and safety profile relative to existing drug therapies for acromegaly. In the five clinical studies completed to date in healthy subjects and patients with acromegaly outside the United States, a beneficial reduction of GH was observed, and, when compared with octreotide, there

was no or less reduction of insulin. COR-005 has been granted orphan drug designation by the FDA and the EMA. We plan to initiate nonclinical animal studies and formulation development activities during 2015 and plan to have a pre-IND meeting with the FDA and a Scientific Advice meeting in Europe in the first half of 2016 prior to advancing COR-005 into further studies and pivotal clinical trials. In addition to a dose-ranging clinical trial, we anticipate that our clinical program will include at least one multinational pivotal clinical trial for registration comparing COR-005 to other treatments or placebo, including at least six months of controlled treatment to evaluate efficacy and one year of observation to evaluate safety.

We believe the development of two product candidates, each with distinct and differentiated mechanisms of action to treat acromegaly could potentially enable us to address the broad acromegaly patient population requiring drug therapy.

Overview of Acromegaly

Acromegaly is a rare endocrine disorder that most commonly results from a benign tumor of the pituitary gland, or adenoma, leading to excess production of GH and IGF-1, key regulators of growth and metabolism. High levels of GH over-activate receptors resulting in excess IGF-1 in patients with acromegaly. A common criterion for the successful treatment of acromegaly is normalization of IGF-1 levels, since reduction of excess IGF-1 correlates closely with relief of clinical symptoms.

The progression of acromegaly is typically slow, and acromegaly often is not clinically diagnosed for 10 years or more. As the disease advances, patients typically exhibit abnormal growth throughout the body. Acromegaly most commonly affects middle-aged patients with the mean age of onset being 40 to 45 years. In adults, the condition results in the expansion of the circumference of bones and increased density of bone, causing pain and altered appearance. This altered appearance is most apparent in the head and face, but also impacts the entire body. Patients may experience abnormal cartilage growth and pressure in joints, enlargement of visceral organs and cardiovascular disease. Upper airway obstruction with sleep apnea occurs in approximately 40% to 50% of patients, and is associated with both soft tissue laryngeal airway obstruction and central sleep dysfunction. Patients may also experience metabolic disruptions such as insulin resistance and diabetes, which is estimated to develop in 10% to 15% of patients. In addition, some patients with large tumors experience symptoms caused by the tumor itself, including headaches, vision problems, impotence, low sex drive and changes in the menstrual cycle. These problems, if left untreated, lead to disfigurement, disability, and ultimately premature death.

We estimate the current acromegaly drug therapy market, including octreotide and lanreotide for acromegaly and total pegvisomant, to be approximately \$990 million worldwide. Based on recent publications, we estimate the diagnosed prevalence of acromegaly to be approximately 24,000 in the United States, and approximately 43,000 in the European Union. Prevalence estimates vary considerably and it is believed that acromegaly is underdiagnosed. Estimates of the mortality rate in patients with acromegaly varies, with published estimates reporting values as high as 2.7 times normal.

Current Treatment Landscape and Limitations on Current Treatment Options

Initial treatment for acromegaly is usually surgery with or without radiation therapy. An estimated 80% of patients are eligible for surgery. The initial surgical cure rate is estimated at approximately 80% to 90% for patients with microadenomas, which are tumors less than 10 mm in diameter, and less than 50% for patients with macroadenomas, which are tumors greater than 10 mm in diameter. Three percent to 10% of patients will experience a recurrence in the years following an initially successful surgery. An estimated 40% to 50% of acromegaly patients will be prescribed for drug therapy, including those for whom surgery is not feasible, is contraindicated or has been unsuccessful. This represents approximately 9,600 to 12,000 patients in the United States and 17,000 to 22,000

patients in the European Union. The goal of drug therapy is primarily to normalize IGF-1 levels and GH levels. Currently, SSAs are the most commonly used drug therapy for the treatment of patients with acromegaly. Up to one-half of treated patients do not adequately respond to SSAs with full IGF-1 normalization and need alternative or adjunctive drug therapies.

Somatostatin is a naturally occurring cyclic peptide, which is a biological molecule consisting of linked amino acids. Somatostatin inhibits the secretion of a broad array of hormones secreted by the pituitary gland, the pancreas and the gastrointestinal tract, or the GI tract, including GH, insulin and glucagon. It also modulates the rate of gastric emptying, the flow of bile from the gallbladder and intestinal blood flow, and inhibits the growth of normal and tumor cells. These functions are mediated primarily by the binding of somatostatin to a family of five SSTRs. There is considerable overlap between activation of these different receptors and their effects on biological functions. GH secretion is inhibited by activation of some of these receptors.

Pituitary adenomas express various patterns of SSTRs depending on whether they produce primarily GH, ACTH or other pituitary hormones. This excessive production leads to acromegaly, Cushing's disease or other diseases, respectively. SSAs are structurally similar to somatostatins and have a therapeutic effect in pituitary adenomas, since they bind to the SSTRs on these tumors and inhibit secretion of hormones such as GH or ACTH. Currently approved SSAs used to treat acromegaly are: octreotide which is available in two formulations, one that is typically injected three times a day, or TID, subcutaneously (Sandostatin), and a second that is a long-acting intramuscular depot for monthly injection (Sandostatin LAR); lanreotide (Somatuline), a slow release or autogel formulation for deep subcutaneous injection once a month; and pasireotide available as a long-acting intramuscular depot for monthly injection (Signifor LAR).

There is a significant unmet need in the treatment of acromegaly. Although long-acting SSAs are the most commonly used drugs, they have several limitations, including:

- Variable efficacy: Estimates of responder rate vary significantly by study design, but the proportion of patients who are effectively managed on SSAs is believed to be between 45% and 70%.
- Disruption of glucose metabolism: SSAs can inhibit insulin and glucagon secretion, potentially leading to an exacerbation of glucose control issues already experienced by some acromegaly patients. Clinical trials with all approved SSAs for acromegaly showed increased rates of hyperglycemia and hypoglycemia, and pasireotide also showed an increased rate of diabetes.
- Tolerability issues due to gastrointestinal side effects: Up to one-third of patients experience gastrointestinal side effects, which can often be transient, but sometimes may require the adjustment of dosing or choice of drug. Up to 62% of patients have gallbladder complications, such as gallstones or sludge in the gallbladder.
- Convenience: Some SSA drugs need to be reconstituted before injection, leading to difficulty with patient self-injection, and often necessitating monthly office visits to receive injections.

While long-term monthly administration controls GH hypersecretion in two-thirds of treated patients, some patients do not respond to SSAs with full IGF-1 normalization and need to move to other drug therapies, which are used as alternatives to or in combination with SSAs. These additional drug therapies also aim to reduce IGF-1. Somavert (pegvisomant) is a human GH receptor antagonist that binds to the GH receptor, but does not activate the mediators leading to IGF-1 production and secretion, thereby acting as a functional GH receptor antagonist, or blocker. The resulting clinical effect is a dose-dependent inhibition of IGF-1. However, because it is administered as a subcutaneous injection on a daily basis, we believe patient acceptance and compliance may be reduced. Dopamine receptor agonists such as cabergoline also inhibit GH secretion by pituitary adenomas expressing the

dopamine receptor, which leads to a moderate inhibition of IGF-1. This class of drugs is not approved by the FDA for the treatment of acromegaly.

A number of products are currently in development for the treatment of acromegaly that may potentially compete against COR-004 and COR-005. The majority of compounds in development for the treatment of acromegaly are reformulations of octreotide acetate that potentially offer improved convenience to patients and physicians. While such compounds may mitigate gastrointestinal side effects and treatment burdens associated with existing SSAs, they are unlikely to address the market's key unmet need for drugs with an improved efficacy and safety profile. As a result, there remains a need for a safe, tolerable and effective drug therapy for acromegaly patients.

Our Solutions—COR-004 and COR-005

COR-004—A Novel Second-Generation Antisense Oligonucleotide

COR-004 is a second-generation antisense oligonucleotide in Phase 2 clinical development for the treatment of acromegaly. Antisense technology consists of introducing an oligonucleotide, a short DNA or RNA molecule with a complementary sequence to a mRNA. mRNA molecules are an intermediate step between genes encoded by DNA and expression of functional proteins. By binding to the target mRNA for the GHR, COR-004 prevents the production of the GHR, primarily in the liver. The GHR is required for GH to bind and exert its effect, including IGF-1 production. By reducing GHRs to which GH binds in the liver, COR-004 effectively reduces IGF-1 levels. This mechanism is distinct from that of SSAs, which inhibit GH secretion in the pituitary by binding to somatostatin receptors. This mechanism is also different from that of pegvisomant, which is a human growth hormone analog that has been structurally altered to act as a GH receptor antagonist, meaning it binds to the GHR without triggering effects at the GHR.

COR-004 has been studied in patients with acromegaly who have had an inadequate response to surgery or candidates for whom surgery is not appropriate. COR-004 may be used in a similar fashion to the current use of pegvisomant, primarily as an alternative or adjunctive drug therapy in the significant proportion of patients who do not respond adequately to SSAs. Due to its novel mechanism of action, COR-004 may have a differentiated safety and efficacy profile compared to pegvisomant. In contrast to daily administration of pegvisomant, we intend to position COR-004 to be labeled for once- or twice-weekly administration, which may be viewed as a convenience advantage, potentially leading to improved patient compliance. In addition, we plan to develop COR-004 to be packaged in pre-filled syringes, eliminating the need for reconstitution, in contrast to most other drug therapies for acromegaly. We intend to seek orphan drug designation for COR-004 from the FDA and the EMA.

Completed Clinical Trials

COR-004 has been dosed as subcutaneous injection in 50 subjects in two clinical trials to date, including a Phase 1 safety and pharmacokinetic clinical trial in 36 healthy subjects, 12 of which received placebo, as well as a Phase 2 efficacy clinical trial in 26 patients with acromegaly. In both clinical trials, COR-004 showed a dose-dependent tolerability profile consistent with other antisense oligonucleotides. The Phase 2 clinical trial showed a statistically significant reduction in IGF-1 levels. A second Phase 2 clinical trial with a higher dose of COR-004 is currently being conducted in four patients by Antisense Therapeutics Limited, or Antisense Therapeutics, from whom we in-licensed this product candidate. All studies to date have been conducted outside of the United States. We plan to conduct Phase 3-enabling chronic toxicology studies in two animal species and in parallel to seek a pre-IND meeting with the FDA in the second half of 2015 to discuss requirements for entry into Phase 3 clinical development.

The following table summarizes these trials. At the time the trials described below were conducted by Antisense Therapeutics Limited, COR-004 was named 1103.

Clinical Trial Number	Clinical Trial Descriptions	Subjects Enrolled	Year and Status	Location	Dose
1103-CT03	Phase 2 Open-Label Trial of the Efficacy, Pharmacokinetics, Safety and Tolerability of COR-004 in Adult Patients with Acromegaly	4	Ongoing.	Australia	300 mg twice weekly
1103-CT02	Phase 2 Randomized, Open-Label Trial of the Safety, Tolerability, Pharmacokinetics and Efficacy of Two Dosing Regimens of COR-004 in Adult Patients with Acromegaly	26	2013/2014 Completed. Study report not yet issued.	United Kingdom, France, Spain, Australia	200 mg once or twice weekly
1103-CT01	Phase 1 Randomized, Placebo-Controlled, Double-Blind Trial of COR-004 in Healthy Male Subjects	36	2011 Completed. Study report issued.	Australia	Single and multiple ascending dose up to 400 mg

Ongoing Phase 2 Clinical Trial

1103-CT03 Clinical Trial

This clinical trial, 1103-CT03, is a randomized, open-label dose ranging Phase 2 clinical trial to evaluate the efficacy, pharmacokinetics, safety and tolerability of subcutaneous doses of COR-004 in adult patients with acromegaly. This study is being conducted by Antisense Therapeutics. This clinical trial is a 13 week treatment of twice weekly subcutaneous injections of 300 mg of COR-004 in four patients with acromegaly. Patient recruitment is underway. The primary and secondary endpoints are similar to those in Study 1103-CT02.

Completed Phase 2 Clinical Trials

1103-CT02 Clinical Trial

The completed Phase 2 clinical trial for COR-004 was a randomized, open-label, parallel group clinical trial of the safety, tolerability, pharmacokinetics and efficacy of two subcutaneous administration regimens of COR-004 in 26 adult patients with acromegaly. Two COR-004 administration regimens were tested for 13 weeks with two months of follow-up: 200 mg three times in the first week then once weekly thereafter or 200 mg three times in the first week then twice weekly thereafter. The primary endpoints were to evaluate the safety and tolerability of COR-004 in patients with acromegaly and to evaluate the single dose and multiple dose pharmacokinetic profiles of COR-004 via the subcutaneous route in patients with acromegaly. The secondary endpoints were to evaluate the effect on IGF-1 and other efficacy outcomes related to acromegaly, such as level of GH, ring size assessment and quality of life assessment. The clinical trial was conducted in 13 sites in the European Union and Australia.

No drug-related serious adverse events were observed, and no patients discontinued the study prematurely due to an adverse event. Reported adverse events included mild to moderate injection site reactions, mild increase in liver transaminases, and mild and transient thrombocytopenia, or a decrease in platelets. Pharmacokinetic analysis revealed that drug levels in blood were still increasing at week 13, at the time of the scheduled end of administration. Thus, the magnitude of the effect on IGF-1 reduction might be higher if patients are dosed over a longer period.

The Phase 2 clinical trial also met its key efficacy endpoint showing a statistically significant average reduction in the serum IGF-1 levels of 26% from baseline, with a p-value of less than 0.0001, at week 14 (one week past the last dose) at the twice weekly (400 mg per week) dose tested. Two patients showed normalized IGF-1 during therapy at week 14. A significant decrease in ring size as a measure of finger size, as an objective measure of soft tissue overgrowth, was observed as well as an

improvement in quality of life. The clinical trial also demonstrated a statistically significant reduction in GH binding protein, with a p-value of 0.0186 at week 14, which indicates a reduction in GHR.

Phase 1 Clinical Trial

1103-CT01 Clinical Trial

The completed Phase 1 clinical trial for COR-004 was a randomized, placebo-controlled, double-blind, single ascending dose and multiple dose clinical trial. COR-004 was administered in four dose cohorts of 25 mg, 75 mg, 250 mg and 400 mg single subcutaneous doses and two cohorts (250 mg or placebo) for multiple doses (six injections over three weeks). In the clinical trial, a total of 24 healthy adult male subjects 18 to 45 years of age received COR-004, and 12 subjects received placebo.

No serious adverse events were reported in the Phase 1 clinical trial. Injection site reactions were observed in a dose-dependent manner. Flu-like illness was limited to the highest 400 mg dose during single administration. Small increases in liver transaminases as well as small decreases in platelet count were also observed. There were no other notable safety or tolerability issues reported.

In the multiple dose stage of the clinical trial, six once-daily doses of COR-004, 250 mg were associated with a small but statistically significant reduction in mean serum IGF-1 concentration of 7% below baseline.

COR-005—A Novel Somatostatin Analog

COR-005, or somatoprim, also referred to as DG3173, is a novel multi-receptor targeted SSA in Phase 2 clinical development for the treatment of acromegaly. In contrast to approved SSAs, COR-005 activates a different subset of SSTRs. Like pasireotide, it activates SSTR2 and SSTR5. However, in contrast to pasireotide, it possesses a higher affinity for SSTR2 than SSTR5. COR-005 is also the only SSA with a high affinity for SSTR4. COR-005 does not bind to SSTR3 or the opiate receptor at physiological concentrations. While the functional consequences of the binding of SSAs to the opiate receptor are not fully understood, it has been suggested as a mechanism contributing to inhibition of insulin secretion by SSAs and may also influence their effect on gastrointestinal motility. *In vitro* data suggest that a higher number of adenomas are a target for GH inhibition by COR-005 as compared to octreotide, which is referred to as a single receptor targeted SSA that binds predominantly to SSTR2 only, potentially resulting in an increased responder rate. Preclinical data from animal studies, and clinical data in healthy subjects and patients with acromegaly, showed that insulin secretion was less inhibited, potentially resulting in reduced side effects on blood glucose and an improved safety and tolerability profile. Preclinical data further suggest a reduced effect on gallbladder motility, or flow from the gallbladder.

In four clinical trials with single subcutaneous injections or infusion and in one six-day clinical trial, all of which were conducted with an immediate release formulation of COR-005 in healthy subjects or patients with acromegaly, COR-005 was observed to have a tolerability profile comparable to that of octreotide. However, unlike octreotide, subjects treated with COR-005 were observed to have less or no reduction in peak insulin secretion after a meal. We believe these preliminary clinical findings corroborate the profile of COR-005 observed in preclinical studies, which suggested inhibition of GH secretion without or with reduced detrimental effects on post-meal insulin or glucose metabolism. These studies were too short to assess the effect on flow from the gallbladder. These preliminary findings contrast favorably with the well-described insulin and glucose perturbations caused by octreotide, lanreotide and pasireotide, and we intend to conduct additional clinical trials to evaluate the clinical profile of COR-005 and its differentiation from existing SSAs. With the potentially superior efficacy, safety and tolerability profile suggested by preclinical studies and early clinical trials, we believe COR-005 has the potential to become the standard-of-care SSA, with distinct therapeutic advantages relative to currently approved SSAs as treatment of acromegaly.

Completed Clinical Trials

Five clinical trials of COR-005 have been performed to date: three in healthy male volunteers and two in patients with acromegaly, all of which employed an immediate release, short-acting formulation injected subcutaneously. At the time the clinical trials described below were conducted, COR-005 was named DG3173. These trials were conducted by Aspireo Pharmaceuticals Ltd., other than DG3173-I-001, which was conducted by Develogen AG.

The following table summarizes these trials.

Clinical Trial Number	Clinical Trial Descriptions	Subjects Enrolled	Year and Status	Location	Dose
DG3173-II-02	Phase 2 The Effect of Subcutaneous Infusion of Three Doses of COR-005 on Growth Hormone Levels in Untreated Acromegaly Patients	8	2013/2014 Completed. Bioanalytical report issued.	Ukraine	920-5520 µg continuous infusion over 23 hours
DG3173-II-01	Phase 2 Trial of the Effect of COR-005 and 300 µg Octreotide on Human Growth Hormone Levels in Untreated Acromegaly Patients	20	2012 Completed. Study report issued.	Ukraine	300-1800 µg QD
DG3173-I-003	Phase 1 Placebo-Controlled, Phase 1 Trial to Assess the Pharmacodynamics Effect on Glucose Metabolism of Single Doses Compared to COR-005 Octreotide and Placebo in Healthy Male Subjects	8	2013 Completed. Study report issued.	Switzerland	300-1800 µg QD
DG3173-I-002	Phase 1 Trial to Compare the Safety and Pharmacologic Activity of Repeated Doses of COR-005 and COR-005 Plus Octreotide with Octreotide and Placebo and Establish Their Pharmacokinetic Interaction in Healthy Male Subjects	42	2012/2013 Completed. Study report issued.	Switzerland	100-1800 µg TID
DG3173-I-001	Phase 1 Double-Blind Trial to Investigate Safety, Tolerability and Pharmacokinetics of Single Escalating Dosing of COR-005 in Healthy Male Subjects	72	2008 Completed. Study report issued.	Germany	10-2000 µg QD

The clinical trials involved 122 healthy subjects in the Phase 1 trials and 28 patients with acromegaly in the Phase 2 clinical trials. No serious adverse events were observed, and mostly mild adverse events typical for SSAs such as injection site reactions and gastrointestinal side effects were reported. There was no evidence that COR-005 adversely affects the liver, kidneys or other organ systems, including the cardiovascular system. Data from the multiple ascending dose clinical trial in healthy subjects (Study I-002) and single ascending dose trial in patients with acromegaly (Study II-01 and II-02) showed inhibition of GH comparable to octreotide, but no or less inhibition of insulin secretion and less effect on glucose levels.

Phase 2 Clinical Trials

DG3173-II-02 Clinical Trial

This clinical trial was an open-label, crossover, active- and placebo-controlled, continuous 23-hour infusion, randomized dose-ranging clinical trial in eight male or female acromegaly patients. COR-005 at doses of 920 µg, 2760 µg, and 5520 µg per 23 hours were infused in a random visit sequence at a rate of 0.04 mg, 0.12 mg, and 0.24 mg per hour spaced one week apart. The placebo, saline, was always infused one week prior to COR-005, and octreotide at a dose of 300 µg was injected TID one week after the last COR-005 dose. Patients had not received any specific treatment for acromegaly in the 12 months prior to the clinical trial and had to have blood IGF-1 concentration greater than or equal to 1.2 times the upper limit of normal reference range adjusted for age plus

random blood GH greater than or equal to 5 µg/L in the 12 months prior to the clinical trial and increased values at screening.

Final results from the clinical trial are not yet available, pending final data validation and analysis. Preliminary safety data indicates no serious adverse events or clinical trial discontinuations due to adverse events.

DG3173-II-01 Clinical Trial

This clinical trial was an open-label, single-center, single-dose, active-controlled, cross-over clinical trial in 20 male or female acromegaly patients. In a fixed sequence with one week washout between treatments, untreated patients received octreotide 300 µg and then each of four doses of subcutaneous COR-005 (100 µg, 300 µg, 900 µg, 1800 µg in that sequence).

Patients had not received any specific treatment for acromegaly in the 12 months prior to the trial and had to have blood IGF-1 concentration greater than or equal to 1.2 times the upper limit of normal reference range adjusted for age, plus random blood growth hormone greater than or equal to 5 µg/L in the six months prior to the trial. Mean age was 48 years, 90% were female, and mean body mass index was 29. Thirteen patients had received prior treatment for acromegaly, including nine with prior surgery (three of these with subsequent radiation therapy), and nine with medications.

GH values were obtained at baseline, or prior to treatment, and for eight hours after each treatment. GH was rapidly suppressed by all treatments, and the effect of COR-005 was dose-dependent, both in terms of suppression extent and duration of effect. The 1800 µg dose of COR-005 and octreotide maximally suppressed GH to a similar extent (mean percentage change 60% for each), with a slightly lesser suppression with the 900 µg dose of COR-005. This suppression resulted in a similar proportion of patients achieving GH levels less than or equal to 2.5 ng/mL among the two highest doses of COR-005 and octreotide (37% to 42%). Also, the time to achieve maximal suppression was shorter for the two highest doses of COR-005 than for octreotide (median two hours for octreotide compared to one hour for the maximally effective COR-005 dose). However, the duration of GH suppression following single dosing was longer for octreotide than COR-005 at all doses, resulting in greater suppression by octreotide of GH as measured by AUC 0 to 8 hours (octreotide 60% mean percentage suppression compared to COR-005 1800 µg 37% mean percentage suppression). We intend to optimize the formulation of COR-005 to prolong exposure, which should lead to increased sustained GH suppression.

Fasting glucose was assessed at screening and at eight hours after each dose. Mean glucose concentrations during COR-005 treatments were similar to the screening values, but were elevated by approximately 2.8 mmol/L after eight hours of treatment with octreotide. Glucose values for octreotide were always determined shortly after clinical trial entry. In contrast, glucose values for the higher doses of COR-005 were drawn several weeks after trial entry. Participation in the clinical trial *per se* would be expected to result in improved glucose control due to observed behavioral changes in trial participants.

There were no serious adverse events. Three out of the 20 patients reported a combined total of three adverse events. One adverse event, a moderately severe headache reported in a 62 year old female as encephalopathy exacerbation, led to early clinical trial discontinuation after the 300 µg dose of COR-005 follow-up visit. The patient who discontinued early had long-standing acromegaly with a very high IGF-1 at baseline (5.5x upper limit of normal, or ULN) and a history of encephalopathy. The investigator considered the relationship to study drug as unassessable. Pharmacokinetic outcomes for COR-005 were similar to those from Phase 1 clinical trials.

Phase I Clinical Trials

DG3173-I-003 Clinical Trial

This clinical trial was a single-blind, placebo- and active-controlled, single ascending dose, randomized cross-over clinical trial in eight healthy male subjects, aged 18 to 45 years. Octreotide at a dose of 300 µg and COR-005 at doses of 300 µg, 900 µg and 1800 µg were injected subcutaneously in random order following a mixed meal test, with four- to five-day washouts between administrations.

Relative to placebo, both COR-005 and octreotide were associated with a delay in the time to peak post-meal insulin. However, the magnitude of peak insulin was similar between placebo and COR-005. In contrast, octreotide delayed and suppressed insulin release during the meal, with peak insulin diminished by 81% and AUC by 62% relative to placebo. The differences in all of these measures, including time to peak, magnitude of peak and AUC, between COR-005 and octreotide were statistically significant with a p-value of less than 0.02 for all parameters. Relative to placebo, all four injections were associated with post-meal glucose excursions. The effect of COR-005 on glucose AUC was dose-related. Glucose was maintained at a high level for a longer time following octreotide relative to COR-005. The glucose AUC for octreotide during the test was elevated relative to all doses of COR-005.

Peak post-meal glucagon was not influenced appreciably by COR-005, whereas a suppression by 50% relative to placebo was observed for octreotide. There was a modest effect of COR-005 at 900 µg and 1800 µg doses, with up to 28% suppression of glucagon AUC. In contrast, octreotide had a pronounced effect on glucagon AUC, suppressed by 63% relative to placebo.

There were no serious adverse events. Adverse events were mostly mild in severity and did not result in any discontinuations. Injection site redness or itching and gastrointestinal system-related complaints (most commonly diarrhea) were the most commonly reported adverse events for both octreotide and COR-005.

DG3173-I-002 Clinical Trial

This clinical trial was a single-blind, placebo- and active-controlled, multiple escalating dose clinical trial in 42 healthy male subjects, aged 18 to 45 years. COR-005 was given TID eight hours apart from days two through eight. There were seven clinical trial groups, with six subjects total per group. In the first four clinical trial groups, four subjects received COR-005 in doses that ranged from 100 µg to 1800 µg TID, one received octreotide 300 µg TID, and one received placebo. In the three remaining clinical trial groups, four subjects received COR-005 plus octreotide, one received placebo plus placebo and one received octreotide plus placebo.

The effects of COR-005 with or without added octreotide on GH, insulin and glucose levels were ascertained using a growth hormone-releasing hormone, or GHRH, test on days one (pretreatment) and three. COR-005 and octreotide given as monotherapy for four doses both suppressed the GHRH-induced rise in GH, with 900 µg of COR-005 approximately equivalent to 300 µg of octreotide, with mean AUC reductions compared to pre-drug administrations of 65% and 70%, respectively, whereas the 1800 µg dose of COR-005 gave somewhat better reduction, with mean AUC reduction of 85%. When the two drugs were used in combination, a maximum suppression of GH response was noted during administration of the COR-005 900 µg. The highest dose of COR-005 1800 µg was not tested in combination with octreotide. Insulin levels were suppressed following treatment with octreotide by 50% from pre-drug, whereas no such effect was noted during COR-005 administrations. Blood glucose concentrations were mostly stable following GHRH infusion. Glucose levels were observed to be similar before and after administrations of both COR-005 and octreotide. There was no clear effect of either drug or saline given alone or in combination with the exception of

COR-005 300 µg, for which glucose levels tended to be lower after administration, both alone and in combination with octreotide.

COR-005 was generally well-tolerated and a maximum tolerated dose was not reached. Adverse events were mostly mild in severity. Injection site redness, itching and gastrointestinal system-related complaints (most commonly diarrhea) were the most commonly reported adverse events and appeared to occur in similar percentages of octreotide- and COR-005-treated subjects. There was small to no accumulation of COR-005 in plasma after repeated doses. Exposure to COR-005 was dose proportional and linear after the first and last doses. When COR-005 was given concomitantly with octreotide 300 µg TID, COR-005 pharmacokinetics were similar to COR-005 given alone.

DG3173-I-001 Clinical Trial

This clinical trial was a double-blind, placebo controlled, single ascending dose clinical trial in 72 healthy male subjects, age 18 to 45 years. A single subcutaneous dose ranging between 10 µg to 2000 µg of COR-005 or placebo was administered under fasting conditions. COR-005 was generally well-tolerated, and the maximum tolerated dose was not reached.

There were no serious adverse events. There were 21 adverse events reported in 15 subjects of which twenty were regarded as mild in severity and one was moderate (diarrhea, 800 µg dose). The time to maximum drug concentration in blood was generally within one hour. Maximum drug concentration in blood generally increased proportionally with dose. The cumulative urinary excretion of drug was proportional to dose ingested, and fractional excretion was consistently about 4% to 5% of the respective doses administered.

In an exploratory pharmacodynamic analysis, GH plasma concentrations were consistent with the suppression of GH by COR-005.

Planned Clinical Trials

We are planning clinical trials of COR-005 to establish the optimal dosage range for normalization of IGF-1 in chronic treatment of acromegaly using a proprietary subcutaneous-injection formulation currently under development. More than one formulation may be used during later clinical development. In addition, we anticipate that at least one multinational pivotal clinical trial for registration comparing COR-005 to other treatments and/or a placebo injection will be required prior to filing for marketing authorizations in key international markets. We may also need to assess pharmacokinetics, safety and efficacy in patients with liver or kidney disease. We are planning a pre-IND meeting with the FDA and a Scientific Advice meeting in Europe in the first half of 2016 prior to advancing COR-005 into further studies and pivotal clinical trials. In addition to a formulation and dosing range clinical trial, we anticipate that our clinical program will include at least one multinational pivotal clinical trial for registration comparing COR-005 to other treatments or placebo, including at least six months of controlled treatment to evaluate efficacy and one year of observation to evaluate safety.

As a next generation SSA with potential growth-inhibitory effects on other pituitary tumors, COR-005 may also have utility in treating other rare endocrine diseases. We plan therefore to explore the utility of COR-005 in Cushing's disease and neuroendocrine tumors in small pilot studies in the respective patient populations.

Other Product Candidates

BP-2001 for the Treatment of Diabetes

BP-2001 is a novel, preclinical-stage, orally delivered biological therapeutic for diabetes. BP-2001 is a genetically modified lactobacillus bacteria. Unmodified lactobacilli are natural probiotics

that exist in the human GI tract and have been shown to be beneficial in a number of ways when taken orally. The BP-2001 technology advances this approach into a novel therapeutic application for diabetes. The genetically engineered lactobacilli are engineered to express full-length (1-37) glucagon-like peptide-1, or GLP-1, and deliver it into the GI tract. The GLP-1 acts as a signaling molecule to trigger the transformation of intestinal enteroendocrine cells into glucose-responsive insulin secreting cells.

In an animal model for diabetes, treatment with BP-2001 was observed to result in a reduction in hyperglycemia. Diabetic rats that were fed daily with human lactobacilli engineered to secrete GLP-1(1-37) showed significant increases in insulin levels and were significantly more glucose tolerant than those fed the unmodified bacterial strain. These rats developed insulin-producing cells within the upper intestine in numbers sufficient to replace 25% to 33% of the insulin capacity of nondiabetic healthy rats. We plan to file an IND for BP-2001 during the first half of 2016 to investigate the safety and pharmacokinetics as well as explore efficacy in patients with type 2 diabetes and currently plan to out-license the technology for further development for the treatment of diabetes.

Commercialization Strategy

Given our current stage of product development, we do not have a commercialization infrastructure. We intend to independently commercialize our rare disease-focused product candidates, if approved, in the United States, the European Union and other key global markets. We believe that we can address the markets for all three of our current product candidates by targeting endocrinologists that are focused on the treatment of rare pituitary disorders primarily stemming from benign tumors. Given the relatively concentrated specialty prescriber base, we plan to create a sales force of approximately 30 representatives in each of the United States and the European Union to market our endocrine product candidates, if approved. In building our sales force, we intend to recruit representatives with experience calling on endocrinologists or marketing orphan drug designated products.

Our commercial strategy for our product candidates, if approved, will encompass promoting their benefits compared to other treatment alternatives, as well as a concerted effort to raise awareness about the underlying disease among physicians with the goal of increasing the rate of diagnosis when the symptoms may otherwise be overlooked. We believe the combination of our commercial effort and our product candidate profiles will facilitate our ability to successfully penetrate our target markets.

In-Licensing and Acquisition Agreements

On May 13, 2015, we entered into an exclusive license agreement, or the License Agreement, with Antisense Therapeutics that provides us with development and commercialization rights to Antisense Therapeutics' product candidate, ATL1103, for endocrinology applications, but specifically excluding the treatment of any form of cancer and the treatment of any complications of diabetes. We refer to this product candidate as COR-004. Under the terms of the License Agreement, we paid Antisense Therapeutics an initial upfront license fee of \$3.0 million in cash, and we also invested \$2.0 million in Antisense Therapeutics equity. We may become obligated to make additional payments, contingent upon achieving specific development and commercialization milestones, of up to \$105.0 million over the lifetime of the License Agreement. We may also be required to make royalty payments based on a percentage, ranging up to the mid-teens, of net sales of COR-004, if approved. Such royalty payment rates and milestone amounts may be reduced upon the occurrence of certain development or patent protection related events. We will be responsible for the future clinical development of COR-004 in endocrinology applications and for the funding of associated future development, regulatory and drug manufacture costs. We are permitted to sublicense our rights under the License Agreement to affiliates or third parties for purposes of assisting with the development or distribution of COR-004, subject to certain notice or sublicense payment provisions. Antisense

Therapeutics will retain commercialization rights for COR-004 in endocrinology applications in Australia and New Zealand, but cannot, and cannot allow its subsidiaries to, conduct any marketing or promotion of COR-004 in endocrinology applications anywhere else in the world. Antisense Therapeutics will also retain worldwide rights for COR-004 in other indications, and may utilize new COR-004 data generated by us in pursuing these other indications, subject to specified terms and conditions. Antisense Therapeutics has the responsibility to prosecute and maintain COR-004's patent protection anywhere in the world, excluding Australia and New Zealand, until the start of a Phase 3 clinical trial, after which we have the responsibility. We also have the primary responsibility to control the preparation, filing, maintenance and prosecution of any patents or patent applications for COR-004 anywhere in the world, excluding Australia and New Zealand. Either party may terminate the License Agreement upon the occurrence of certain events, provided notice is given to the other party. We may terminate the License Agreement upon 90 days' prior written notice to Antisense Therapeutics if we believe the further development and commercialization of COR-004 is no longer feasible due to a material change that is beyond our control. If, however, we terminate the License Agreement for convenience upon 90 days' prior written notice to Antisense Therapeutics prior to the filing of an NDA in the United States for COR-004, we must pay Antisense Therapeutics a \$2.0 million termination fee.

On June 30, 2015, we acquired from Aspireo Pharmaceuticals Ltd., an Israeli company, its product candidate, DG3173. We refer to this product candidate as COR-005. Under the terms of the acquisition agreement, we issued to Aspireo Pharmaceuticals 2,062,677 common shares, which had a value of \$33.2 million on June 30, 2015. In connection with this acquisition, we made a payment to OCS in the amount of \$3.0 million, which represents the repayment of amounts previously granted by OCS to Aspireo Pharmaceuticals, plus interest, that were used in support of research and development conducted by Aspireo Pharmaceuticals for the development of DG3173. The approval by OCS of the transfer of the assets relating to DG3173 by Aspireo to the Company was subject to the repayment of the original grant plus interest.

On March 30, 2011, a license agreement was executed between BioPancreate and the Cornell Center for Technology Enterprise and Commercialization (CCTEC). Under the terms of the license agreement, BioPancreate obtained certain rights from the CCTEC for commercial development, use and sale of products that use the technology associated with the license.

License issue fees payable to the CCTEC include \$15,000 paid within 30 days after the execution of the agreement (Effective Date) and \$235,000 to be paid in five equal installments of \$47,000 payable annually within 30 day of the Effective Date's respective anniversary. As of December 31, 2014, there were two remaining installments to be paid. We are obligated to make milestone payments upon the achievement of certain regulatory and clinical milestones up to \$2.6 million in the aggregate. For years in which licensed products are sold, we are required to pay a royalty based on a low single-digit percentage of net sales. The minimum annual royalty in such years is \$100,000.

In the event the product is sublicensed, up to \$3.5 million of certain fees we receive that are not earned royalties or reimbursements for direct costs are due to the CCTEC upon achievement of certain regulatory and clinical milestones.

Manufacturing

The manufacturing, packaging and distribution of COR-003 drug product for clinical trials following Good Manufacturing Practices, or GMPs, is currently outsourced under contracts to third parties. We expect to enter into similar arrangements for our other drug product candidates.

Intellectual Property

We actively seek to protect the intellectual property and proprietary technology that we believe is important to our business, including seeking, maintaining, enforcing and defending patent rights for our product candidates and methods of treatment, whether developed internally or licensed from third parties. Our success will depend on our ability to obtain and maintain patent and other protection including data or market exclusivity for our product candidates and methods of treatment, preserve the confidentiality of our know-how and operate without infringing the valid and enforceable patents and proprietary rights of third parties.

Our policy is to seek to protect our proprietary position generally by filing patent applications initially at the USPTO. After this initial phase, patent applications claiming priority to the initial application are filed in various countries, including the United States, Europe and Canada. In each case, we determine the strategy and territories required after discussion with our patent professionals with the goal of obtaining relevant coverage in territories that are commercially important to us and our product candidates. We will additionally rely on data exclusivity and patent term extensions when available, including the relevant exclusivity through orphan drug designation. We also rely on trade secrets and know-how relating to our underlying product technologies. Prior to making any decision on filing any patent application, we consider with our patent professionals whether patent protection is the most sensible strategy for protecting the invention concerned or whether the invention should be maintained as confidential.

As of July 14, 2015, we owned or licensed 84 granted patents, of which 12 are U.S.-issued patents, and 34 pending patent applications, of which six are U.S. patent applications.

As of September 3, 2015, we have one pending United States, one pending Canadian and one pending International (Madrid Protocol) trademark application designating Australia, China, European Community, India, Israel, Japan, Mexico, and Turkey for the mark “Strongbridge Biopharma.”

COR-003

We own 41 granted patents related to our product candidate, COR-003. Issued claims in these patents are directed to methods of treatment of various diseases or conditions associated with elevated cortisol levels or activity using COR-003. The patents have been granted in major territories including Europe, China and Japan. We have two patent applications pending in the United States directed to methods of treating a disease or condition associated with elevated cortisol levels or activity with COR-003, and methods of reducing C-reactive protein levels and reducing systemic inflammation with COR-003. We also have four pending foreign or PCT patent applications for next-generation product candidates, including new chemical entities. Patents in this portfolio, if and when issued, are expected to expire in 2026 and 2027 if there are no patent term adjustments or extensions.

COR-004

We license eight granted patents directed to compounds used for modulation of growth hormone receptor expression and insulin-like growth factor expression, methods of reducing the plasma level of insulin-like growth factor-1, methods of treating an animal having a disease or condition associated with growth hormone receptor signaling or the growth hormone/insulin-like growth factor axis, and methods of reducing the expression of growth hormone receptor, all with COR-004. Patents have been granted in major territories, including the United States, Japan and Canada. The U.S. patents expire in 2024 and 2025. We have two patent applications pending in the United States and nine foreign applications pending worldwide with claims directed to methods of reducing the serum level of growth hormone binding protein using COR-004 and methods of treating or preventing a disease caused by and/or associated with an increased level of insulin-like growth factor using COR-004.

COR-005

While we own granted patents in the United States and other major territories, including Europe, Canada and Japan, the terms of the patents may not extend beyond the launch date of this product candidate. We intend to rely on orphan and data/marketing exclusivity for COR-005.

Laws and Regulations Regarding Patent Terms

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the earliest date of filing a non-provisional application. In the United States, a patent term may be shortened if a patent is terminally disclaimed over another patent or as a result of delays in a patent prosecution by the patentee. A patent's term may be lengthened by a patent term adjustment, which compensates a patentee for administrative delays by the USPTO in granting a patent. The patent term of a European patent is 20 years from its effective filing date, which, unlike in the United States, is not subject to patent term adjustments in the same way as U.S. patents.

The term of a patent that covers an FDA-approved drug or biologic may also be eligible for patent term extension, which permits patent term restoration as compensation for the patent term lost during the FDA regulatory review process. The Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, permits a patent term extension of up to five years beyond the expiration of the patent. The length of the patent term extension is related to the length of time the drug or biologic is under regulatory review. Patent extensions cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only one patent applicable to an approved drug may be extended. Similar provisions are available in Europe and other jurisdictions to extend the term of a patent that covers an approved drug, for example Supplementary Protection Certificates. In the future, if and when our products receive FDA approval, we expect to apply for patent term extensions on patents covering those products. We anticipate that some of our issued patents may be eligible for patent term extensions but such extensions may not be available and therefore our commercial monopoly may be restricted.

Competition

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. While we believe that our scientific knowledge, technology, and development experience provide us with competitive advantages, we face potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions. Any product candidates that we successfully develop and commercialize will compete with existing products and new products that may become available in the future. Many of our competitors, alone or with their strategic partners, have greater experience than we do in conducting preclinical studies and clinical trials, and obtaining FDA, EMA and other regulatory approvals, and have substantially greater financial, technical and other resources than we do, such as larger research and development, clinical, marketing and manufacturing organizations. As a result, these companies may obtain regulatory approval for competing products more rapidly than we are able and may be more effective in selling and marketing their products. Companies that complete clinical trials, obtain required regulatory authority approvals and commence commercial sale of their drugs before their competitors may achieve a significant competitive advantage, and our commercial opportunity could be reduced or eliminated if competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Drugs resulting from our research and development efforts or from our joint efforts with collaboration partners therefore may not be commercially competitive with our competitors' existing products or products under development.

We are aware of several companies focused on developing or marketing therapies for rare endocrine disorders. For our product candidates, the main competitors include:

- **COR-003:** A number of therapies are currently approved and in various stages of development for endogenous Cushing's syndrome. Currently, the marketed therapies for the treatment of endogenous Cushing's syndrome patients who fail or are ineligible for surgery in the United States and Europe are: Korlym (mifepristone) marketed by Corcept Therapeutics in the United States; and Signifor (pasireotide) marketed by Novartis in the European Union, and ketoconazole, metyrapone and mitotane marketed by HRA in the European Union. Additionally, Signifor (pasireotide) LAR and LCI-699 are currently in Phase 3 clinical development by Novartis in Cushing's disease patients.
- **COR-004 and COR-005:** A number of SSA therapies are currently approved and in various stages of development for acromegaly. There are currently four approved SSA therapies for acromegaly: Sandostatin LAR (octreotide) marketed by Novartis; Signifor LAR (pasireotide) marketed by Novartis; Somatuline depot (lanreotide) marketed by Ipsen; and Somavert (pegvisomant) marketed by Pfizer. Six additional therapies are in late-stage clinical development for acromegaly: octreotide acetate oral formulation (RG-3806) developed by Chiasma; octreotide solid-dose injectable (GP-02) developed by Glide Pharma and Canadian licensee Paladin Labs; ITF-2984 developed by Italfarmaco; octreotide LAR depot developed by GP Pharma; octreotide long-acting depot (CAM-2029) developed by Novartis; and octreotide sustained release developed by Q-Chip.
- **BP-2001:** The diabetes landscape is crowded with a number of therapies supported by large pharmaceutical organizations with significant resources. BP-2001 is in early pre-clinical development and the competitive landscape will likely evolve significantly as the product approaches commercialization, if approved.

Government Regulation

Product Approval Process

The clinical testing, manufacturing, labeling, storage, distribution, record keeping, advertising, promotion, import, export and marketing, among other things, of our product candidates are subject to extensive regulation by governmental authorities in the United States and other countries. The FDA under the Federal Food, Drug, and Cosmetic Act regulates pharmaceutical products in the United States. The steps required before a drug may be approved for marketing in the United States generally include:

- the completion of preclinical laboratory tests and animal tests conducted under Good Laboratory Practices, or GLPs, and other applicable regulations;
- the submission to the FDA of an IND application for human clinical testing, which must be reviewed by the FDA and become effective before human clinical trials commence;
- the successful performance of adequate and well-controlled human clinical trials conducted in accordance with Good Clinical Practices to establish the safety and efficacy of the product candidate for each proposed indication;
- analysis of clinical trial data and preparation of submission to the FDA of an NDA;
- the submission to the FDA of an NDA;
- the FDA's acceptance of the NDA;

- satisfactory completion of an FDA inspection of the manufacturing facilities at which the product is made to assess compliance with cGMPs to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;
- satisfactory completion of FDA inspections of clinical trial sites and GLP toxicology studies; and
- the FDA's review and approval of an NDA prior to any commercial marketing or sale of the drug in the United States.

The testing and approval process requires substantial time, effort and financial resources, and the receipt and timing of any approval is uncertain.

Preclinical studies include laboratory evaluations of the product candidate, as well as animal studies to assess the potential safety and efficacy of the product candidate. The results of the preclinical studies, together with manufacturing information, analytical data and a proposed clinical trial protocol, are submitted to the FDA as part of the IND, which must become effective before clinical trials may be commenced. The IND will become effective automatically 30 days after receipt by the FDA, unless the FDA raises concerns or questions about the conduct of the clinical trials as outlined in the IND prior to that time and places the IND on clinical hold. In this case, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can proceed. A clinical hold may occur at any time during the life of an IND, due to safety concerns or non-compliance, and may affect one or more specific studies or all studies conducted under the IND.

Clinical trials involve the administration of the product candidates to healthy volunteers or patients with the disease to be treated under the supervision of a qualified principal investigator. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, the parameters to be used in monitoring safety, and the efficacy criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. Further, each clinical trial must be reviewed and approved by an independent institutional review board, or IRB, either centrally or individually at each institution at which the clinical trial will be conducted. The IRB will consider, among other things, ethical factors, the safety of human subjects and the possible liability of the institution. Progress reports detailing the status of the clinical trials must be submitted to the FDA annually. Sponsors must also report to the FDA serious and unexpected adverse reactions, any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigation brochure, or any findings from other studies or animal or *in vitro* testing that suggest a significant risk in humans exposed to the drug. There are also requirements governing the reporting of ongoing clinical trials and clinical trial results to public registries.

Clinical trials are typically conducted in three sequential phases prior to approval, but the phases may overlap. These phases generally include the following:

- Phase 1. Phase 1 clinical trials represent the initial introduction of a product candidate into human subjects, frequently healthy volunteers. In Phase 1, the product candidate is usually tested for safety, including adverse effects, dosage tolerance, absorption, distribution, metabolism, excretion and pharmacodynamics.
- Phase 2. Phase 2 clinical trials usually involve studies in a limited patient population to (1) evaluate the efficacy of the product candidate for specific indications, (2) determine dosage tolerance and optimal dosage, and (3) identify possible adverse effects and safety risks.
- Phase 3. Phase 3 clinical trials are conducted to further demonstrate clinical efficacy, optimal dosage and safety within an expanded patient population at geographically dispersed clinical trial sites, and to provide sufficient data for the statistically valid evidence of safety and efficacy.

Phase 4 clinical trials are conducted after approval to gain additional experience from the treatment of patients in the intended therapeutic indication and to document a clinical benefit in the case of drugs approved under accelerated approval regulations, or when otherwise requested by the FDA in the form of post-market requirements or commitments. Failure to promptly conduct any required Phase 4 clinical trials could result in withdrawal of approval.

Clinical trials are inherently uncertain and any phase may not be successfully completed. A clinical trial may be suspended or terminated by the FDA, IRB or sponsor at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides ongoing oversight and safety reviews to determine whether or not a clinical trial may move forward at designated check points based on access to certain data from the clinical trial. We may also suspend or terminate a clinical trial based on evolving business objectives and/or competitive climate.

Sponsors have the opportunity to meet with the FDA at certain points during the development of a new drug to share information about the data gathered to date and for the FDA to provide advice on the next phase of development. These meetings may be held prior to the submission of an IND, at the end of Phase 2 and/or before an NDA is submitted. Meetings may be requested at other times as well.

The results of preclinical studies and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information on the manufacture, composition and quality of the product, proposed labeling and other relevant information are submitted to the FDA in the form of an NDA requesting approval to market the product. The NDA must be accompanied by a significant user fee payment. The FDA has substantial discretion in the approval process and may refuse to accept any application, for example if the NDA is not sufficiently complete, or decide that the data is insufficient for approval and require additional preclinical, clinical or other studies.

In addition, under the Pediatric Research Equity Act, or PREA, an NDA or supplement to an NDA must contain data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of data or full or partial waivers. Unless otherwise required by regulation, PREA does not apply to any drug for an indication for which orphan drug designation has been granted. However, if only one indication for a product has orphan drug designation, a pediatric assessment may still be required for any applications to market that same product for the non-orphan indication(s).

Once the NDA submission has been submitted, the FDA has 60 days after submission of the NDA to conduct an initial review to determine whether it is sufficient to accept for filing. NDAs receive either a standard or priority review. Under the Prescription Drug User Fee Act, the FDA sets a goal date by which it plans to complete its review. For a standard review, this is typically 12 months from the date of submission of the NDA application. The review process is often extended by FDA requests for additional information or clarification. Before approving an NDA, the FDA will inspect the facilities at which the product is manufactured and will not approve the product unless the manufacturing facility complies with cGMPs and may also inspect clinical trial sites for integrity of data supporting safety and efficacy. The FDA may also convene an advisory committee of external experts to provide input on certain review issues relating to risk, benefit and interpretation of clinical trial data. The FDA is not bound by the recommendations of an advisory committee, but generally follows such recommendations in making its decisions. The FDA may delay approval of an NDA if applicable regulatory criteria are not satisfied and/or the FDA requires additional testing or information. The FDA may require post-marketing testing and surveillance to monitor safety or efficacy of a product.

After the FDA evaluates the NDA and conducts inspections of manufacturing facilities where the drug product and/or its API will be produced, it may issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. A Complete Response Letter generally outlines the deficiencies in the NDA submission and may require substantial additional clinical testing, such as an additional pivotal Phase 3 clinical trial(s), clinical data, and/or other significant, expensive and time consuming requirements related to clinical trials, preclinical studies or manufacturing. Even if such additional information is submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval.

The FDA may approve the NDA with a Risk Evaluation and Mitigation Strategy, or REMS, plan to mitigate risks, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling, development of adequate controls and specifications, or a commitment to conduct one or more post-market studies or clinical trials. Such post-market testing may include Phase 4 clinical trials and surveillance to further assess and monitor the product's safety and effectiveness after commercialization.

Orphan Drug Designation

Under the Orphan Drug Act of 1983, the FDA may grant orphan drug designation to a drug or biological product intended to treat an orphan disease or condition, which is a disease or condition that affects fewer than 200,000 individuals in the United States, or if it affects more than 200,000 individuals in the United States, there is no reasonable expectation that the cost of developing and making a drug product available in the United States for this type of disease or condition will be recovered from sales of the product. Orphan product designation must be requested before submitting an NDA. After the FDA grants orphan product designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan product designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product that has orphan drug designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications to market the same drug or biological product for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity. The designation of such drug also entitles a party to financial incentives, such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. Competitors, however, may receive approval of different products for the indication for which the orphan product has exclusivity or obtain approval for the same product but for a different indication for which the orphan product has exclusivity. Orphan product exclusivity also could block the approval of one of our products for seven years if a competitor obtains approval of the same drug or biological product as defined by the FDA or if our product candidate is determined to be contained within the competitor's product for the same indication or disease. If a drug product designated as an orphan product receives regulatory approval for an indication broader than that for which it is designated, it may not be entitled to orphan product exclusivity. Orphan drug status in the European Union has similar but not identical benefits in that jurisdiction.

Post-Approval Requirements

Drugs manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product distribution, advertising and promotion, and reporting of

adverse experiences with the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval and may require additional clinical trials and NDA submissions. There also are continuing, annual user fee requirements for any marketed products and the establishments at which such products are manufactured, as well as new application fees for supplemental applications with clinical data.

In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and state agencies, and are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained, or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information, imposition of post-market studies or clinical trials to assess new safety risks, or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, but are not limited to:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending NDAs or supplements to approved NDAs, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

Moreover, the recently enacted federal Drug Supply Chain Security Act imposes new obligations on manufacturers of pharmaceutical products, among others, related to product tracking and tracing. Among the requirements of this new federal legislation, manufacturers will be required to provide certain information regarding the drug product to individuals and entities to which product ownership is transferred, label drug product with a product identifier, and keep certain records regarding the drug product. Further, under this new legislation, manufacturers will have drug product investigation, quarantine, disposition, and notification responsibilities related to counterfeit, diverted, stolen, and intentionally adulterated products, as well as products that are the subject of fraudulent transactions or which are otherwise unfit for distribution such that they would be reasonably likely to result in serious health consequences or death.

Foreign Regulation

In order to market any product outside of the United States, we would need to comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we would need to obtain the necessary approvals by the comparable foreign regulatory authorities before we can commence clinical trials or marketing of the product in foreign countries and jurisdictions. Although many of the issues discussed above with respect to the United States apply similarly in the context of the European Union, the approval process varies between countries and jurisdictions and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries and jurisdictions might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others.

Other Healthcare Laws

In addition to FDA restrictions on the marketing of pharmaceutical products, federal and state healthcare laws restrict certain business practices in the biopharmaceutical industry. Although we currently do not have any products on the market, we may be subject, and once our product candidates are approved and we begin commercialization, will be subject to additional healthcare laws and regulations enforced by the federal government and by authorities in the states and foreign jurisdictions in which we conduct our business. These laws include, but are not limited to, anti-kickback, false claims, data privacy and security, and transparency statutes and regulations.

The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, purchasing, leasing, arranging for, ordering or recommending any good, facility, item or service for which payment is made, in whole or in part, under Medicare, Medicaid or any other federal healthcare programs. The term “remuneration” has been broadly interpreted to include anything of value, including for example, gifts, discounts, the furnishing of supplies or equipment, credit arrangements, payments of cash, waivers of payment, ownership interests and providing anything at less than its fair market value. The federal Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand, and prescribers, purchasers and formulary managers on the other. Although there are a number of statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution, the exceptions and safe harbors are drawn narrowly, and our future practices may not in all cases meet all of the criteria for a statutory exception or safe harbor protection. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable regulatory safe harbor does not make the conduct *per se* illegal under the federal Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. Several courts have interpreted the statute’s intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare program covered business, the statute has been violated. Additionally, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, PPACA, amended the intent requirement under the Anti-Kickback Statute and criminal healthcare fraud statutes (discussed below) such that a person or entity no longer needs to have actual knowledge of the statute or the specific intent to violate it in order to have committed a violation. In addition, PPACA provides that the government may assert that a claim including items or services resulting from a violation of the

federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act (discussed below). Due to the breadth of these federal and state anti-kickback laws, and the potential for additional legal or regulatory change in this area, it is possible that our current and future sales and marketing practices and/or our future relationships with physicians might be challenged under these laws, which could cause harm to us.

The civil monetary penalties statute imposes penalties against any person or entity who, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.

The federal false claims laws prohibit, among other things, any person or entity from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment or approval to the federal government or knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes “any request or demand” for money or property presented to the U.S. government. Recently, several pharmaceutical and other healthcare companies have been prosecuted under these laws for, among other things, allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies’ marketing of the product for unapproved, and thus non-covered, uses.

The Health Insurance Portability and Accountability Act of 1996, or HIPAA, created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, including private third-party payors, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of, or payment for, healthcare benefits, items or services.

In addition, we may be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA’s security standards directly applicable to business associates—independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also created four new tiers of civil monetary penalties, and newly empowered state attorneys general with the authority to enforce HIPAA. In January 2013, the Office for Civil Rights of the U.S. Department of Health and Human Services issued the Final Omnibus Rule under HIPAA pursuant to HITECH that makes significant changes to the privacy, security, and breach notification requirements and penalties. The Final Omnibus Rule generally took effect in September 2013 and enhances certain privacy and security protections, and strengthens the government’s ability to enforce HIPAA. The Final Omnibus Rule also enhanced requirements for both covered entities and business associates regarding notification of breaches of unsecured protected health information. In addition, state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways. These state laws may not have the same effect and often are not preempted by HIPAA, thus complicating compliance efforts.

Additionally, PPACA also included the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program (with certain

exceptions) to report annually information related to certain payments or other transfers of value made or distributed to physicians and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals and to report annually certain ownership and investment interests held by physicians and their immediate family members. Failure to comply with required reporting requirements could subject applicable manufacturers and others to substantial civil money penalties.

Also, many states have similar healthcare statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Certain states require pharmaceutical companies to implement a comprehensive compliance program that includes a limit or outright ban on expenditures for, or payments to, individual medical or health professionals and/or require pharmaceutical companies to track and report gifts and other payments made to physicians and other healthcare providers.

Because we intend to commercialize products that could be reimbursed under federal and other governmental healthcare programs, we plan to develop a comprehensive compliance program that establishes internal controls to facilitate adherence to the rules and healthcare program requirements. Although compliance programs and adherence thereto may mitigate the risk of violation of and subsequent investigation and prosecution for violations of the above laws, the risks cannot be entirely eliminated. If our operations are found to be in violation of any of the health care laws or regulations described above or any other laws that apply to us, we may be subject to penalties, including potentially significant criminal, civil and/or administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion of products from reimbursement under government programs, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings and/or the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. To the extent that any of our products will be sold in a foreign country, we may be subject to similar foreign laws and regulations, which may include, for instance, applicable post-marketing requirements, including safety surveillance, fraud and abuse laws, and implementation of corporate compliance programs and reporting of payments or transfers of value to healthcare professionals.

Pharmaceutical Coverage, Pricing and Reimbursement

In both domestic and foreign markets, our sales of any future approved products, if and when commercialized, will depend in part on the availability of coverage and adequate reimbursement from third-party payors. Third-party payors include government authorities, managed care providers, private health insurers and other organizations. Patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients are unlikely to use our products, if approved, unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products. Sales of our products will therefore depend substantially, both domestically and abroad, on the extent to which the costs of our products will be paid by third-party payors. These third-party payors are increasingly focused on containing healthcare costs by challenging the price and examining the cost-effectiveness of medical products and services.

In addition, significant uncertainty exists as to the coverage and reimbursement status of newly approved healthcare product candidates. The market for our product candidates for which we may receive regulatory approval will depend significantly on access to third-party payors' drug formularies, or lists of medications for which third-party payors provide coverage and reimbursement. The industry competition to be included in such formularies often leads to downward pricing pressures on pharmaceutical companies. Also, third-party payors may refuse to include a particular branded drug in their formularies or otherwise restrict patient access to a branded drug when a less costly generic equivalent or other alternative is available. Furthermore, third-party payor reimbursement to providers

for our product candidates may be subject to a bundled payment that also includes the procedure administering our products. To the extent there is no separate payment for our product candidates, there may be further uncertainty as to the adequacy of reimbursement amounts. Because each third-party payor individually approves coverage and reimbursement levels, obtaining coverage and adequate reimbursement is a time consuming, costly and sometimes unpredictable process. We may be required to provide scientific and clinical support for the use of any product to each third-party payor separately with no assurance that approval would be obtained, and we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost-effectiveness and/or medical necessity of our products. This process could delay the market acceptance of any product and could have a negative effect on our future revenues and operating results. We cannot be certain that our product candidates will be considered cost-effective or medically necessary. Because coverage and reimbursement determinations are made on a payor-by-payor basis, obtaining acceptable coverage and reimbursement from one payor does not guarantee the Company will obtain similar acceptable coverage or reimbursement from another payor. A payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. If we are unable to obtain coverage of, and adequate reimbursement and payment levels for, our product candidates from third-party payors, physicians may limit how much or under what circumstances they will prescribe or administer them and patients may decline to purchase them. This in turn could affect our ability to successfully commercialize our products and impact our profitability, results of operations, financial condition and future success.

Furthermore, in many foreign countries, particularly the countries of the European Union, the pricing of prescription drugs is subject to government control. In some non-U.S. jurisdictions, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. We may face competition for our product candidates from lower-priced products in foreign countries that have placed price controls on pharmaceutical products. In addition, there may be importation of foreign products that compete with our own products, which could negatively impact our profitability.

Healthcare Reform

In the United States and foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system that could affect our future business and operations if and when we begin to directly commercialize our products.

In particular, there have been and continue to be a number of initiatives at the U.S. federal and state level that seek to reduce healthcare costs. Initiatives to reduce the federal deficit and to reform healthcare delivery are increasing cost-containment efforts. We anticipate that Congress, state legislatures and the private sector will continue to review and assess alternative controls on healthcare spending through limitations on the growth of private health insurance premiums and Medicare and Medicaid spending, the creation of large insurance purchasing groups, price controls on pharmaceuticals and other fundamental changes to the healthcare delivery system. Any proposed or actual changes could limit or eliminate our spending on development projects and affect our ultimate profitability.

In March 2010, PPACA was signed into law. PPACA has substantially changed the way healthcare is financed by both governmental and private insurers. PPACA, among other things: established an annual, nondeductible fee on any entity that manufactures or imports certain branded

prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs; revised the methodology by which rebates owed by manufacturers for covered outpatient drugs under the Medicaid Drug Rebate Program are calculated; increased the statutory minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program; addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted, or injected; extended the Medicaid Drug Rebate Program to prescriptions of individuals enrolled in Medicaid managed care organizations; required manufacturers to offer 50% point-of-sale discounts on negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D; and implemented payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models.

In the future, there may continue to be additional proposals relating to the reform of the U.S. healthcare system, some of which could further limit the prices we will be able to charge for our product candidates, or the amounts of reimbursement available for our product candidates. If future legislation were to impose direct governmental price controls and access restrictions, it could have a significant adverse impact on our business. Managed care organizations, as well as Medicaid and other government agencies, continue to seek price discounts. Some states have implemented, and other states are considering, measures to reduce costs of the Medicaid program, and some states are considering implementing measures that would apply to broader segments of their populations that are not Medicaid-eligible. Due to the volatility in the current economic and market dynamics, we are unable to predict the impact of any unforeseen or unknown legislative, regulatory, payor or policy actions, which may include cost containment and healthcare reform measures. Such policy actions could have a material adverse impact on our profitability.

Employees

As of June 30, 2015, we had 13 full-time employees. Of these full-time employees, 4 were engaged in research and development and 8 were engaged in general and administrative activities, including business and corporate development. None of our employees is subject to a collective bargaining agreement or represented by a trade or labor union. We consider our relations with our employees to be good.

Properties and Facilities

We lease 14,743 square feet of office space at 900 Northbrook Drive, Suite 200, Trevose, Pennsylvania 19053 for research and development and administrative activities. We believe that our existing facility is adequate to meet our current needs, and that suitable additional alternative spaces will be available in the future on commercially reasonable terms. We also lease 3,173 square feet of office space in Radnor, Pennsylvania, and intend to pursue opportunities to sublease this office space.

Legal Proceedings

We are not currently a party to any material legal proceedings.

MANAGEMENT

Executive Officers and Board of Directors

The following table presents information about our officers and directors as of October 14, 2015.

<u>NAME</u>	<u>AGE</u>	<u>POSITION</u>
Executive Officers		
Matthew Pauls	45	Chief Executive Officer and Director
Ruth Thieroff-Ekerdt, M.D.	58	Chief Medical Officer
A. Brian Davis	48	Chief Financial Officer
Stephen Long	50	Chief Legal Officer
Robert Lutz	46	Chief Business Officer
Non-Employee Directors		
John H. Johnson	57	Director, Chairman of the Board
Richard S. Kollender	46	Director
Garheng Kong, M.D., Ph.D.	40	Director
Mårten Steen, M.D., Ph.D.	40	Director
Hilde H. Steineger, Ph.D.	49	Director

Unless otherwise indicated, the current business addresses for our executive officers and directors is 900 Northbrook Drive, Suite 200, Trevose, Pennsylvania 19053, United States.

Executive Officers

Matthew Pauls has served as our Chief Executive Officer since August 2014 and as a member of our board of directors since September 2015. Prior to joining Strongbridge, Mr. Pauls was Chief Commercial Officer of Insméd, Inc., a publicly traded biopharmaceutical company, from April 2013 to August 2014. Prior to Insméd, Mr. Pauls worked at Shire Pharmaceuticals, a publicly traded specialty biopharmaceutical company, beginning in 2007 until March 2013, most recently as Senior Vice President, Head of Global Commercial Operations. Mr. Pauls also held positions at Bristol-Myers Squibb, a publicly traded pharmaceutical company, in Brand Management and Payor Marketing, and at Johnson & Johnson, a publicly traded medical devices, pharmaceutical and consumer packaged goods manufacturer, in various U.S. and global commercial roles. He is a volunteer board member of the Pennington School in Pennington, New Jersey, and the Boys & Girls Clubs of Philadelphia. Mr. Pauls holds B.S. and M.B.A. degrees from Central Michigan University and a J.D. from Michigan State University College of Law.

Ruth Thieroff-Ekerdt, M.D. has served as our Chief Medical Officer since December 2014. Prior to joining Strongbridge, Dr. Thieroff-Ekerdt was Chief Medical Officer at Aptalis Pharmaceuticals, a pharmaceutical company, from February 2011 to February 2014. Aptalis Pharmaceuticals was acquired in February 2014 by Forest Laboratories. Aptalis Pharmaceuticals was formed in 2011 after the acquisition of Eurand Pharmaceuticals, a specialty pharmaceutical company focused on gastrointestinal diseases, where Dr. Thieroff-Ekerdt served as Chief Medical Officer beginning in 2008 until January 2011. Prior to that, Dr. Thieroff-Ekerdt held positions of increasing leadership in clinical and research functions at Bayer Consumer Care and Bayer Schering Pharmaceuticals (formerly Berlex Inc. and Schering AG). Dr. Thieroff-Ekerdt received her M.D. as well as a Dr. med degree from the Free University Berlin in Germany. She has additional training in pharmacology and toxicology, including training in clinical pharmacology.

A. Brian Davis has served as our Chief Financial Officer since March 2015. Prior to joining Strongbridge, Mr. Davis served as Senior Vice President and Chief Financial Officer at Tengion, Inc., a

publicly traded regenerative medicine company, from August 2010 to December 2014. In December 2014, Tengion, Inc. filed a petition for relief under Chapter 7 of Title 11 of the United States Bankruptcy Code. From 2009 to July 2010, Mr. Davis served in a consulting capacity as Chief Financial Officer of Neose Technologies, Inc., a biopharmaceutical company. Mr. Davis worked at Neose Technologies, Inc. from 1994 to 2009, where he held several positions of increasing responsibility, including Senior Vice President and Chief Financial Officer. Mr. Davis is licensed as a certified public accountant, and received a B.S. in accounting from Trenton State College and an M.B.A. from The Wharton School at the University of Pennsylvania.

Stephen Long has served as our Chief Legal Officer since March 2015. Prior to joining Strongbridge, Mr. Long served as Counsel at the law firm of Reed Smith LLP, from April 2013 to February 2015. He previously served at C.R. Bard, Inc., a medical device manufacturing company, from October 2000 to May 2012 in the roles of Vice President, General Counsel, as Vice President, and Secretary, and as Associate General Counsel. Mr. Long also served as Assistant General Counsel, Consumer Healthcare, at Warner-Lambert Company, and as Counsel for the company's pharmaceutical division from February 1998 to September 2000. Mr. Long held positions earlier in his career at the law firm of Willkie Farr & Gallagher and Bankers Trust Company. Mr. Long received his B.S. from the School of Industrial and Labor Relations at Cornell University and his J.D. from Albany Law School of Union University.

Robert Lutz has served as our Chief Business Officer since October 2014. Prior to joining Strongbridge, he worked as a full-time consultant at Medgenics, a publicly traded, early-stage, gene-therapy and rare disease biotech company, from May 2014 to September 2014. Mr. Lutz worked at Shire Pharmaceuticals, a publicly traded specialty biopharmaceutical company, from November 2012 to April 2014, where he most recently served as Vice President and held key leadership positions in the Neurosciences Business unit. Prior to Shire Pharmaceuticals, Mr. Lutz worked in a variety of roles, including Vice President and Senior Associate, for Cinergy Corp., an electric and gas utility company. Mr. Lutz worked as a Senior Analyst at Alan B. Slifka and Co., a hedge fund, after having started his career at Goldman Sachs, where he served as a Financial Analyst in their principal investment area. He holds a B.A. in economics and computer science from Amherst College and an M.B.A. from the Kellogg School of Management.

Non-Employee Directors

John H. Johnson has served as Chairman of our board of directors since March 2015. From January 2012 until August 2014, Mr. Johnson served as the President and Chief Executive Officer of Dendreon Corporation and as its Chairman from January 2012 until June 2014. From January 2011 until January 2012, he served as the Chief Executive Officer and a member of the board of Savient Pharmaceuticals, Inc. From November 2008 until January 2011, Mr. Johnson served as Senior Vice President and President of Eli Lilly and Company's Oncology unit. He was also Chief Executive Officer of ImClone Systems Incorporated, which develops targeted biologic cancer treatments, from August 2007 until November 2008, and served on ImClone's board of directors until it was acquired by Eli Lilly in November 2008. From 2005 to 2007, Mr. Johnson served as Company Group Chairman of Johnson & Johnson's Worldwide Biopharmaceuticals unit, President of its Ortho Biotech Products LP and Ortho Biotech Canada units from 2003 to 2005, and Worldwide Vice President of its CNS, Pharmaceuticals Group Strategic unit from 2001 to 2003. Prior to joining Johnson & Johnson, he also held several executive positions at Parkstone Medical Information Systems, Inc., Ortho-McNeil Pharmaceutical Corporation and Pfizer, Inc. Mr. Johnson is the former Chairman of Tranzyme Pharma, Inc. Mr. Johnson currently serves as a member of the board of directors of Cempra Pharmaceuticals, Inc., Histogenics Corporation, Portola Pharmaceuticals, Inc. and Sucampo Pharmaceuticals, Inc. He previously served as a member of the board of directors for the Pharmaceutical Research and Manufacturers of America and the Health Section Governing Board of

Biotechnology Industry Organization. Mr. Johnson holds a B.S. from the East Stroudsburg University of Pennsylvania.

Richard S. Kollender has served as a member of our board of directors since March 2015. Since January 2011, he has served as a Partner and Executive Manager of Quaker Partners Management, LP, a healthcare investment firm, which he initially joined in 2003, and was promoted to Partner in 2005. Mr. Kollender serves as a director of Celator Pharmaceuticals, Inc., Rapid Micro BioSystems and Tarsa Therapeutics. Mr. Kollender previously served as a director of Insmmed, Inc., Transave, Inc., Nupathe, Inc., TargetRx, Inc., Precision Therapeutics, Inc., Transport Pharmaceuticals, Inc., and Corridor Pharmaceuticals. Mr. Kollender also held positions in sales, marketing and worldwide business development at GlaxoSmithKline, or GSK, and served as investment manager at S.R. One, the corporate venture capital arm of GSK. Mr. Kollender holds a B.A. in accounting from Franklin and Marshall College and practiced as a Certified Public Accountant for six years in public accounting at firms including KPMG.

Garheng Kong, M.D., Ph.D. has served as a member of our board of directors since September 2015. In July 2013, he founded, and has since served as managing partner of, HealthQuest Capital, a healthcare venture growth fund focused on medical products, devices, diagnostics, consumer health and healthcare IT. Dr. Kong was a general partner at Sofinnova Ventures, a venture firm focused on life sciences, from September 2010 to December 2013. From May 2000 to September 2010, he worked at Intersouth Partners, a venture capital firm, serving most recently as a general partner. Dr. Kong currently serves as a director of Cempra, Inc., Histogenics Corporation, Alimera Sciences, Inc. and Laboratory Corporation of America Holdings. Dr. Kong holds a B.S. from Stanford University and an M.D., Ph.D. and M.B.A. from Duke University.

Mårten Steen, M.D., Ph.D. has served as a member of our board of directors since December 2014. Since April 2010, he has served as a Partner of HealthCap VI LP, a venture capital firm investing in life science companies. Prior to HealthCap, from February 2008 until March 2010, Dr. Steen served as director at Merck Serono SA, a biopharmaceutical company. Currently, he serves as a member of the board of directors of Wilson Therapeutics AB, Vaxin Inc. and BioClin Therapeutics Inc. He previously served on the boards of Ultragenyx Inc. and FerroKin Biosciences. Dr. Steen holds a B.Sc. in Business Administration, an M.D., and a Ph.D. in Clinical Chemistry, all from Lund University.

Hilde H. Steineger, Ph.D. has served as a member of our board of directors since January 2014. She is currently Head of Innovation Management in the Nutrition & Health Division of BASF. She previously served as the Head of Global Omega-3 Innovation Management at Pronova BioPharma ASA, a BASF company, from April 2013 to May 2015. From August 2007 to June 2010, Dr. Steineger was Head of Investor Relations for Pronova BioPharma and Vice President Business Development in Pronova BioPharma from November 2009 to April 2013. Dr. Steineger is a board member and Head of the Audit Committee of Nordic Nanovector ASA. Dr. Steineger also serves as a director of PCI Biotech AS and Afiew AS. She previously served as a member of the board of directors of Algeta ASA, Weifa AS, Invent2 AS, Alertis AS, Clavis ASA and Biotech Pharmacon ASA. Dr. Steineger holds a Ph.D. in medical biochemistry from University of Oslo.

Board Composition

The Irish Companies Act provides for a minimum of two directors. Our Articles provide for a minimum of two directors and a maximum of 13 directors. Our shareholders may from time to time increase or reduce the maximum number, or increase or reduce the minimum number, of directors by ordinary resolution. Our board of directors determines the number of directors within the range of two to 13. Our board currently consists of six directors.

Our Articles divide our board of directors into three classes, with members of each class being elected to staggered three-year terms. At each annual general meeting, directors will be elected for a

full term of three years to succeed those directors of the relevant class whose terms are expiring. A nominee is elected to the board of directors by a plurality of votes cast.

Holders of our ordinary shares are entitled to one vote for each share at all meetings at which directors are elected.

Our Articles provide for a minimum number of directors of two. In the event that an election results in only one director being elected, that director shall be elected and shall serve for a three-year term, and the nominee receiving the next greatest number of votes in favour of his or her election shall hold office until his or her successor shall be elected.

Any vacancy on our board of directors, including a vacancy resulting from an increase in the number of directors or from the death, resignation, retirement, disqualification or removal of a director, shall be deemed a casual vacancy. Subject to the terms of any one or more classes or series of preferred shares, any casual vacancy shall only be filled by the decision of a majority of our board of directors then in office, provided that a quorum is present and provided that the appointment does not cause the number of directors to exceed any number fixed by or in accordance with our Articles as the maximum number of directors.

Any director of a class of directors elected to fill a vacancy resulting from an increase in the number of directors of such class shall hold office for the remaining term of that class. Any director elected to fill a vacancy not resulting from an increase in the number of directors shall have the same remaining term as that of his predecessor. A director retiring at a meeting shall retain office until the close or adjournment of the meeting.

Our Articles provide that our shareholders may, by an ordinary resolution, remove a director from office before the expiration of his or her term. Additionally, our Articles provide that a director may be removed with or without cause at the request of not less than 75% of the other directors.

We are a foreign private issuer. As a result, in accordance with the NASDAQ stock exchange listing requirements of The NASDAQ Global Select Market, or NASDAQ, we may rely on home country governance requirements and certain exemptions thereunder rather than relying on the stock exchange corporate governance requirements. For an overview of our corporate governance principles, see “Description of Share Capital and Articles of Association.”

Director Independence

Based upon information requested from and provided by each director concerning their background, employment and affiliations, including family relationships, our board of directors has determined that each of Messrs. Johnson and Kollender and Drs. Steen, Kong and Steineger, representing five of our six directors, is independent under the applicable rules and regulations of NASDAQ. In making such determinations, the board of directors considered the relationships that each such non-employee director has with our company and all other facts and circumstances the board of directors deemed relevant in determining their independence.

Committees of the Board of Directors

The standing committees of our board of directors consist of a governance committee, an audit committee and a compensation committee. Each committee operates under a charter. Following the closing of this offering, copies of each committee’s charter will be posted on the Investor & Media section of our website, which is located at www.strongbridgebio.com.

Governance Committee

The current members of our governance committee are Mårten Steen and John H. Johnson, with Dr. Steen serving as chairman. Our board of directors has determined that each member of our governance committee is independent under the applicable listing requirements of NASDAQ.

Audit Committee

The current members of our audit committee are Richard S. Kollender, Hilde H. Steineger and John H. Johnson, with Mr. Kollender serving as chairman. Our board of directors has determined that each member of our audit committee is independent under Rule 10A-3 of the Exchange Act and the applicable listing requirements of NASDAQ, and that each member of our audit committee satisfies the other listing requirements of NASDAQ for audit committee membership. Our board of directors has also determined that Mr. Kollender qualifies as an “audit committee financial expert,” as such term is defined by the SEC, and that he has the requisite level of financial sophistication required by the continued listing standards of NASDAQ.

Compensation Committee

The current members of our compensation committee are John H. Johnson and Garheng Kong, with Mr. Johnson serving as chairman. Our board of directors has determined that each member of our compensation committee is independent under the applicable listing requirements of NASDAQ.

EXECUTIVE COMPENSATION

Summary Compensation Table

The following table sets forth information concerning cash and non-cash compensation paid for 2014 to our Chief Executive Officer, our other two most highly compensated executive officers and our former Chief Executive Officer. We refer to these as our named executive officers.

Name and position	Year	Salary (\$)	Bonus (\$) ⁽¹⁾	Stock awards (\$)	Option awards (\$) ⁽²⁾	Non- equity incentive plan compensation (\$)	Non- qualified deferred compensation earnings (\$)	All other compensation (\$)	Total
Matthew Pauls <i>Chief Executive Officer</i>	2014	\$131,026	\$210,000	—	\$441,672	—	—	—	\$782,698
H. Joseph Reiser ⁽³⁾ <i>Former Chief Executive Officer</i>	2014	—	—	—	—	—	—	\$273,287	\$273,287
Robert Lutz <i>Chief Business Officer</i>	2014	\$ 65,753	\$ 25,000	—	\$201,729	—	—	—	\$292,482
Ruth Thieroff-Ekerdt, M.D. <i>Chief Medical Officer</i>	2014	\$ 13,958	—	—	\$253,481	—	—	—	\$267,439

- (1) The amounts in this column represent the discretionary bonuses paid to Mr. Pauls and Mr. Lutz with respect to 2014 performance and a \$10,000 sign-on bonus paid to Mr. Pauls in 2014.
- (2) The amounts disclosed reflect the grant-date fair value of stock options granted in 2014. The grant-date fair value of stock options was determined using the Black-Scholes model, in accordance with FASB ASC Topic 718. For additional information regarding the assumptions used in determining fair value using the Black Scholes pricing model, see Note 10, “Stock Based Compensation and Restricted Shares” to our audited consolidated financial statements included in the this prospectus.
- (3) Mr. Reiser ceased to be our Chief Executive Officer in August 2014, but remained as non-executive chairman through December 2014. During his term as Chief Executive Officer, we compensated Mr. Reiser as a consultant. The column “All other compensation” includes \$150,000 of consulting fees for service through August 2014, \$12,877 of healthcare allowance, \$93,750 of severance and \$16,660 of board fees in his capacity as a director (earned after his service as our Chief Executive Officer). Mr. Reiser’s fees for board service are also reflected in the “Director Compensation” table.

Narrative to Summary Compensation Table

We entered into employment agreements with Matthew Pauls, Robert Lutz and Ruth Thieroff-Ekerdt in 2014 in connection with their hiring. The employment agreements outline the terms of the employment relationship, including any potential severance benefits. We believe that the employment agreements provide some certainty to our management team and help to retain the leadership necessary for our company to succeed.

The exercise price of awards held by our named executive officers as of December 31, 2014 were denominated in Norwegian kroner (NOK) and Swedish kroner (SEK). For purposes of presentation, we have converted the exercise prices into U.S. dollars utilizing exchange rates as of December 31, 2014.

Employment Agreements with Matthew Pauls, Robert Lutz and Ruth Thieroff-Ekerdt

We entered into an employment agreement with (1) Mr. Pauls as of August 23, 2014, for his service as our Chief Executive Officer, (2) Mr. Lutz on October 6, 2014, for his initial service as our Chief Business Officer, and (3) Dr. Thieroff-Ekerdt on December 15, 2014, for her service as our Chief Medical Officer. The term of the employment agreement for Mr. Pauls is through August 23, 2016, the

term of the employment agreement with Mr. Lutz is through October 6, 2017, and the term of the employment agreement for Dr. Thieroff-Ekerdt is through December 15, 2017. The employment agreements will automatically renew for one-year terms unless either party gives notice of non-renewal at least 90 days prior to the end of the term.

Under the terms of the employment agreements Mr. Pauls, Mr. Lutz and Dr. Thieroff-Ekerdt are entitled to receive base salaries of \$400,000, \$275,000 and \$335,000, respectively, and are eligible to receive an annual incentive bonus of up to 50%, 40% and 40% of base salary, respectively. Mr. Pauls was awarded a discretionary bonus of \$200,000 for 2014, and Mr. Lutz was awarded a discretionary bonus of \$25,000 for 2014. Mr. Pauls also received a \$10,000 sign-on bonus. In 2015, our board of directors approved an increase in Mr. Pauls' base salary to \$450,000. Our board of directors approved amendments to the employment agreements with Mr. Pauls, Mr. Lutz and Dr. Thieroff-Ekerdt, which will become effective following the completion of the offering, and which provide for annual incentive bonus targets of 50%, 40% and 40%, respectively.

Mr. Pauls received a grant of options to purchase 227,272 shares of our common stock in connection with his initial hiring on August 23, 2014, and Mr. Lutz and Dr. Thieroff-Ekerdt received grants of 99,999 and 109,089 options, respectively, pursuant to their employment agreements on October 6, 2014 and December 15, 2014, respectively. These stock options vest and become exercisable in three separate tranches, provided the executive is employed by us on such date: the first tranche (72,727 options for Mr. Pauls, 31,818 for Mr. Lutz and 36,363 for Dr. Thieroff-Ekerdt), vests on August 23, 2015, October 6, 2015 and December 15, 2015 with an exercise price of \$8.88 per share for Mr. Pauls and Mr. Lutz, and \$8.82 per share for Dr. Thieroff-Ekerdt; the second tranche (72,727 options for Mr. Pauls, 31,818 for Mr. Lutz and 36,363 for Dr. Thieroff-Ekerdt), with an exercise price of \$11.85 per share for Mr. Pauls and Mr. Lutz, and \$11.76 per share for Dr. Thieroff-Ekerdt, vests on August 23, 2016, October 6, 2016 and December 15, 2016, respectively; and the third tranche (81,818 options for Mr. Pauls, 36,363 for Mr. Lutz and 36,363 for Dr. Thieroff-Ekerdt), with an exercise price of \$14.69 per share for Mr. Pauls and Mr. Lutz, and \$14.58 per share for Dr. Thieroff-Ekerdt, vests on August 23, 2017, October 6, 2017 and December 15, 2017, respectively.

In addition, if at any time prior to second anniversary of the grant date our stock price reaches \$17.71 and remains at such price for one month (using the 30-day average), a portion of each executive's unvested options with the lowest remaining exercise price (72,727 for Mr. Pauls and Mr. Lutz and 36,363 for Dr. Thieroff-Ekerdt) will vest and become exercisable (provided the executive is employed on such date). All options fully vest and become exercisable upon a change in control of our company, and have a term of five years from the date of grant.

Under their agreements, Mr. Pauls, Mr. Lutz and Dr. Thieroff-Ekerdt are entitled to participate in benefits offered by us for similarly situated employees and four weeks of vacation time per calendar year. Dr. Thieroff-Ekerdt is also eligible, during the first six months of her employment, for temporary housing near our headquarters.

Each employment agreement provides for severance benefits detailed below under "Potential Payments upon Terminations of Employment or Following a Change in Control." Each employment agreement also contains a non-competition provision, which applies during the term of employment and for one year following termination, and a restrictive covenant with respect to non-disclosure of confidential information, which remains in effect during the term of employment and at all times thereafter.

We entered into an employment agreement with Mr. Davis in March 2015 upon the commencement of his employment with our company as Chief Financial Officer. The term of the employment agreement for Mr. Davis is through March 23, 2018, and will automatically renew for one-year terms unless either party gives notice of non-renewal at least 90 days prior to the end of the

term. The agreement also provides for additional benefits that are substantially similar to the benefits contained in the employment agreements for similarly situated executives of the company.

Consulting Agreement with H. Joseph Reiser

During the period that Mr. Reiser served as our Chief Executive Officer, he was retained through a consulting agreement. We entered into the consulting agreement on June 1, 2012, and it continued in effect until his services as Chief Executive Officer ended on August 25, 2014, and he remained the non-executive Chairman of the board until December 31, 2014. Pursuant to the consulting agreement, Mr. Reiser received a fee of \$200,000 for each full year of services, paid monthly in arrears; for 2014, this fee was increased to \$225,000 plus a healthcare allowance. Mr. Reiser also received a grant of fully vested options to purchase 181,818 shares of our common stock with an exercise price of \$1.42 per share, and a grant of options to purchase 90,909 additional shares of our common stock with an exercise price of \$5.58 per share that vested by the end of 2012. The options have a term of five years from the date of grant.

Mr. Reiser is also entitled to a bonus in the event that BioPancreate or the major assets derived from the BioPancreate technology are acquired in an asset purchase or sale of the BioPancreate technology to a third party prior to the time BioPancreate would enter a Phase 2b clinical trial initiated by us or December 31, 2016, or the BioPancreate Bonus. The BioPancreate Bonus equals 5% of the acquisition price of BioPancreate, with a cap of \$2.5 million. Mr. Reiser will also be entitled to a bonus upon each occurrence that an asset derived from the BioPancreate technology is licensed by us to a third party prior to the conduct of a Phase 2b clinical trial by us or December 31, 2016, or the Licensing Bonus. The Licensing Bonus equals 5% of the value of any signing fee received by us, with a cap of \$1.25 million per event, provided that the third party agrees to be responsible for all future development costs associated with the development of the licensed asset in the territory licensed, excluding patent costs. In the event the license requires us to finance all or a portion of the development of the asset in the licensed territory, we will pro-rate the signing fee by deducting the estimated future amount of unreimbursed research and development spend by us for the territory, excluding patent costs and/or developmental milestones due to Cornell under the BioPancreate agreement. Both the BioPancreate Bonus and the Licensing Bonus will be paid regardless of whether Mr. Reiser is employed by us at the time of the sale or license.

Other Benefits

Our named executive officers (other than Mr. Reiser) are eligible to participate in our employee benefit plans on the same basis as our other employees, including our health and welfare plans and our 401(k) plan. Under our 401(k) plan, participants may elect to make both pre- and post-tax contributions to their accounts in the plan, and we do not match these contributions. Our named executive officers are not eligible for retirement benefits other than under our 401(k) plan.

Outstanding Equity Awards at December 31, 2014

The following table includes certain information with respect to all equity awards that were outstanding as of December 31, 2014 for our named executive officers.

Name	Option Awards			
	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price (\$) ⁽⁴⁾	Option Expiration Date
Matthew Pauls	—	72,727 ⁽¹⁾	\$ 8.88	8/31/2019
	—	72,727 ⁽¹⁾	\$11.85	8/31/2019
	—	81,818 ⁽¹⁾	\$14.69	8/31/2019
H. Joseph Reiser	181,818	—	\$ 1.42	12/31/2016
	90,909	—	\$ 5.58	12/31/2017
Robert Lutz	—	31,818 ⁽²⁾	\$ 8.88	10/1/2019
	—	31,818 ⁽²⁾	\$11.85	10/1/2019
	—	36,363 ⁽²⁾	\$14.69	10/1/2019
Ruth Thieroff-Ekerdt, M.D.	—	36,363 ⁽³⁾	\$ 8.82	12/15/2019
	—	36,363 ⁽³⁾	\$11.76	12/15/2019
	—	36,363 ⁽³⁾	\$14.58	12/15/2019

(1) These options vest in three equal annual tranches. The first tranche of these options vests on August 23, 2015. The second tranche vests on August 23, 2016. The third tranche vests on August 23, 2017. These options will fully vest and become exercisable upon a “change in control” (as defined in the executive’s employment agreement) provided that the executive is employed on the date of such change in control.

(2) These options vest in three equal annual tranches. The first tranche of these options vests on October 6, 2015. The second tranche vests on October 6, 2016. The third tranche vests on October 6, 2017. These options will fully vest and become exercisable upon a “change in control” (as defined in the executive’s employment agreement) provided that the executive is employed on the date of such change in control.

(3) These options vest in three equal annual tranches. The first tranche of these options vests on December 15, 2015. The second tranche vests on December 15, 2016. The third tranche vests on December 15, 2017. These options will fully vest and become exercisable upon a “change in control” (as defined in the executive’s employment agreement) provided that the executive is employed on the date of such change in control.

(4) The exercise price was converted from NOK or SEK, as applicable, to USD at an exchange rate of 7.436 NOK to 1 USD or 7.812 SEK to 1 USD, which were the respective exchange rates as of December 31, 2014.

Prior to September 3, 2015, we did not have an equity compensation plan. Grants of stock options to the named executive officers and other individuals were made through individual grant agreements.

In May 2015, our board of directors approved additional option grants to Mr. Pauls, Dr. Thieroff-Ekerdt, and Messrs. Davis and Long in the amounts of 454,543, 54,542, 54,542 and 54,542, respectively. These stock options, with an exercise price of \$16.81 per share, vest and become exercisable in three separate tranches, provided the executive is employed by us on such date: the first tranche (151,818 options for Mr. Pauls and 18,181 options for each of Ms. Thieroff-Ekerdt and Messrs. Davis and Long) vests in 16 equal quarterly installments commencing on the grant date; the second tranche (151,363 options for Mr. Pauls and 18,181 options for each of Ms. Thieroff-Ekerdt and Messrs. Davis and Long) vests in 16 equal quarterly installments commencing on the date on which our shares begin trading on NASDAQ; and the third tranche (151,362 options for Mr. Pauls and 18,180 options for each of Ms. Thieroff-Ekerdt and Messrs. Davis and Long) vests one-half on the date on which the closing price of our shares as reported on NASDAQ equals twice the amount of the exercise price of the options for 20 consecutive trading days, so long as this occurs prior to May 26, 2019, and one-half on the one year anniversary of such initial vesting date. All options fully vest and become

exercisable upon a change of control of our company, and have a term of 10 years from the date of grant.

In June 2015, our board of directors approved an additional option grant to Mr. Lutz to purchase 22,724 shares. This option, with an exercise price of \$15.01 per share, vests and becomes exercisable in three separate tranches, provided the executive is employed by us on such date: the first tranche (7,575 shares) vests in 16 equal quarterly installments commencing on the grant date; the second tranche (7,575 shares) vests in 16 equal quarterly installments commencing on the date on which our shares begin trading on NASDAQ; and the third tranche (7,575 shares) vests one half on the date on which the closing price of our shares as reported on NASDAQ equals twice the amount of the exercise price of the options for 20 consecutive trading days, so long as this occurs prior to June 25, 2019, and one half on the one year anniversary of such initial vesting date. The option fully vests and becomes exercisable upon a change of control of our company, and has a term of 10 years from the date of grant.

In July 2015, our board of directors approved option grants to Dr. Thieroff-Ekerdt and Messrs. Davis and Long to purchase 163,179, 133,362, and 133,362 shares, respectively. Each option grant replaces a grant made to each such employee to purchase 109,089 shares in connection with his or her commencement of employment. These stock options, each with an exercise price of \$18.81 per share, vest and become exercisable with respect to one-third of the shares on each of the 12-, 24-, and 36-month anniversaries of employee's commencement of employment with our company (provided employee is employed by our company on each such vest date). If at any time during the 24-month period immediately following the effective date of the grant, our stock price reaches a level 100% greater than the exercise price of Dr. Thieroff-Ekerdt's option (or \$37.62 per share) or a level that is 67% greater than the exercise price of the options granted to Messrs. Davis and Long (or \$31.46 per share) and remains at such level for one month using the 30-day average), one-third of the unvested options with the lowest remaining exercise price will vest and become exercisable, provided the employee is employed by our company on such date. Each of these options fully vests and becomes exercisable upon a change of control of our company, and has a term of 10 years from the date of grant.

Potential Payments Upon Terminations of Employment or Following a Change in Control

The employment agreements with Mr. Pauls, Mr. Lutz and Dr. Thieroff-Ekerdt provide that, upon a termination of employment by our company without "cause," or by the executive for "good reason," subject to the execution of a release of claims, he or she will be entitled to (1) an amount equal to the sum of 18 months of base salary for Mr. Pauls, or 12 months of base salary for Mr. Lutz and Dr. Thieroff-Ekerdt, and the target bonus, paid in installments over the 18-month period following termination for Mr. Pauls or the 12-month period following termination for Mr. Lutz and Dr. Thieroff-Ekerdt, (2) a pro rata portion of the annual bonus that he or she would have been entitled to receive for the calendar year that includes the termination date, based on the actual achievement of the applicable performance goals, and (3) medical and dental benefits provided by us that are at least equal to the level of benefits provided to other similarly situated active employees until the earlier of (a) 18 months following the termination date for Mr. Pauls, or 12 months following the termination date for Mr. Lutz or Dr. Thieroff-Ekerdt and (b) the date the executive becomes covered under a subsequent employer's medical and dental plans.

If Mr. Pauls, Mr. Lutz or Dr. Thieroff-Ekerdt is terminated due to our election not to renew the term of the employment agreement, subject to the execution of a release of claims, he or she will be entitled to (1) an amount equal to the sum of 12 months of base salary for Mr. Pauls, or six months of base salary for Mr. Lutz or Dr. Thieroff-Ekerdt, and the target bonus for Mr. Pauls or one-half of the target bonus for Mr. Lutz and Dr. Thieroff-Ekerdt, paid in installments over the 12-month period following termination for Mr. Pauls or the six-month period following termination for Mr. Lutz or

Dr. Thieroff-Ekerdt, (2) a pro rata portion of the annual bonus that he or she would have been entitled to receive for the calendar year that includes the termination date, based on the actual achievement of the applicable performance goals, and (3) medical and dental benefits provided by us that are at least equal to the level of benefits provided to other similarly situated active employees until the earlier of (a) 12 months following the termination date for Mr. Pauls, or six months following the termination date for Mr. Lutz or Dr. Thieroff-Ekerdt and (b) the date the executive becomes covered under a subsequent employer's medical and dental plans.

In the event there is a change in control of our company and, during the 24-month period following the change in control, Mr. Pauls, Mr. Lutz or Dr. Thieroff-Ekerdt is terminated by us without cause, by the executive for good reason, or due to our election not to renew the term of the employment agreement, he or she will be entitled to the severance benefits detailed above and all unvested equity or equity-based awards held by the executive will accelerate and vest. Our board of directors approved amendments to the employment agreements with Mr. Pauls, Mr. Lutz, and Dr. Thieroff-Ekerdt, which will become effective following the completion of the offering, and which increase (1) the severance payable in the event the executive is terminated during the 24-month period following a change in control to an amount equal to the sum of 24 months base salary and the target bonus for Mr. Pauls and the sum of 18 months base salary and the target bonus for Mr. Lutz and Dr. Thieroff-Ekerdt, paid in installments over the 24-month period following termination for Mr. Pauls or the 12-month period following termination for Mr. Lutz or Dr. Thieroff-Ekerdt; and (2) the medical and dental benefits provided by us until the earlier of (a) 18 months following the termination date for Mr. Pauls or one year following the termination date of Mr. Lutz or Dr. Thieroff-Ekerdt and (b) the date the executive becomes covered under a subsequent employer's medical and dental plans.

Under the employment agreements, "cause" is defined as (1) the conviction of, or plea of guilty or nolo contendere to, any felony or any crime involving theft, embezzlement, dishonesty or moral turpitude, (2) any act constituting willful misconduct, deliberate malfeasance, dishonesty, or gross negligence in the performance of the individual's duties, (3) the willful and continued failure to perform any of the individual's duties, which has not been cured within 30 days following written notice from us, or (4) any material breach by the individual of the employment agreement or any other agreement with us, which has not been cured within 30 days following written notice from us. "Good reason" is defined as any of the following reasons unless cured by us within a specified period: (1) a material reduction of the individual's base salary, other than a reduction that is applicable to other senior executives in the same manner and proportion, (2) the assignment of duties or responsibilities which are materially inconsistent with the individual's position, (3) a change in the principal location at which the individual performs his or her duties to a new location that is more than 50 miles from the prior location or (4) a material breach of the employment agreement by us. "Change of control" is defined as (a) a new entity becomes owner of at least 90% of the issued shares of our company or (b) our company is merged pursuant to Chapter 12 of the Public Limited Liabilities Act 1, whereby we are not the surviving entity and our shareholders are no longer majority owners.

The employment agreements also provide that, in the event that Mr. Pauls, Mr. Lutz or Dr. Thieroff-Ekerdt is subject to the excise tax under Section 4999 of the Code, the payments that would be subject to the excise tax will be reduced to the level at which the excise tax will not be applied unless such executive would be in a better net after-tax position by receiving the full payments and paying the excise tax.

Mr. Reiser's consulting agreement did not provide severance, but required us to give him six months' notice of termination. After his termination on August 25, 2014 as our Chief Executive Officer, we paid him an amount equal to five months of his consulting fees (\$93,750).

Director Compensation

Our directors receive fees in cash for their service on the board. Dr. Steineger, Mr. Jørgensen, and Dr. Steen received fees for 2014 beginning on the date they joined the board of directors. The remaining directors received fees beginning in June 2014. The cash fees for 2014 were equal to \$23,534 for members and \$40,344 for the chairman on a per year basis, pro-rated for the period of service beginning at the AGM in June 2014 to the end of 2014.

Mr. Eichenberg and Mr. Mahady also received a grant of options for their service on the board. Under IFRS, we accounted for these options in 2012 to 2013, but these options are considered to have been granted in 2014 under FASB ASC Topic 718. The number of options granted were determined through a negotiation between the board and Mr. Eichenberg and Mr. Mahady individually. These options are fully vested.

<u>Name</u>	<u>Fees earned or paid in cash (\$)⁽¹⁾</u>	<u>Option awards (\$)⁽²⁾</u>	<u>Total (\$)</u>
H. Joseph Reiser ⁽³⁾	\$16,660	—	\$16,660
Espen Tidemann Jørgensen ⁽³⁾	\$26,441	—	\$26,441
Ernest Eichenberg III	\$15,390	\$39,925	\$55,315
Joseph M. Mahady ⁽⁴⁾	\$15,390	\$46,357	\$61,747
Eigil Stray Spetalen ⁽³⁾	\$19,774	—	\$19,774
Mårten Steen, M.D., Ph.D	\$ 2,266	—	\$ 2,266
Hilde H. Steineger, Ph.D	\$26,441	—	\$26,441

- (1) Represents the amounts of all fees earned and paid in cash for services as a director in 2014. This amount, along with Mr. Reiser's compensation as an executive officer is set forth above under "Executive Compensation."
- (2) Represents the grant date fair value determined in accordance with FASB ASC Topic 718 for option awards granted to our non-employee directors.
- (3) Messrs. Reiser, Jørgensen and Spetalen previously resigned from the board of directors of Cortendo AB and will not serve as directors of Strongbridge Biopharma plc.
- (4) Mr. Mahady resigned from our board of directors effective September 11, 2015.

The board fees paid to our directors during 2014 and exercise price of awards held by our directors as of December 31, 2014 were denominated in Norwegian Kroner (NOK). For purposes of presentation, we have converted the board fees and exercise prices into U.S. dollar utilizing the exchange rates as of December 31, 2014.

Our non-employee directors in 2014 held the following outstanding option awards as of December 31, 2014:

<u>Name⁽¹⁾</u>	<u>Outstanding option awards (#)</u>
Espen Tidemann Jørgensen	—
Ernest Eichenberg III	12,726
Joseph M. Mahady	15,453
Eigil Stray Spetalen	—
Mårten Steen, M.D., Ph.D.	—
Hilde H. Steineger, Ph.D.	—

- (1) Mr. Reiser's outstanding option awards as of December 31, 2014 are set forth above under the caption "Outstanding Equity Awards at December 31, 2014."

In addition, Messrs. Johnson and Kollender were granted options effective upon their election to our board of directors on March 18, 2015 in the amounts of 54,543 and 27,270 options, respectively. These stock options vest and become exercisable in three separate equal tranches on each of the first three anniversaries of the date of grant, with an exercise price of \$11.91, \$14.68 and \$17.69 per share, respectively.

In anticipation of the consummation of this offering, our board of directors adopted a director compensation program that provides for the following:

- Annual Cash Retainer—\$40,000
- Additional Annual Retainers
 - Non-Executive Chairman of the Board Retainer—\$35,000
 - Audit Committee Chair Retainer—\$15,000
 - Compensation Committee Chair Retainer—\$10,000
 - Governance Committee Chair Retainer—\$7,500
 - Audit Committee Member (other than Chairman) Retainer—\$7,500
 - Compensation Committee Member (other than Chairman) Retainer—\$5,000
 - Governance Committee Member (other than Chairman) Retainer—\$3,750
- Equity Compensation
 - Initial Equity Grant—25,000 stock options, with 1/3 of the options vesting on the first anniversary of the date of grant and the remaining 2/3 of the options vesting in equal monthly installments over the 24-month period that follows the first anniversary of the date of grant, provided that the director continues to provide services as a member of our board of directors continuously from the date of grant through the applicable vesting date
 - Annual Equity Grant—15,000 stock options (other than the Non-Executive Chairman of the Board, who will receive 20,000 stock options), with such option vesting in full on the first anniversary of the date of grant, provided that the director continues to provide services as a member of our board of directors continuously from the date of grant through the vesting date

On September 22, 2015, our board of directors granted 25,000 stock options to each of Mårten Steen, Hilde Steineger and Garheng Kong as their initial equity grant, which options will become effective upon the pricing of this offering, with an exercise price equal to the higher of (i) the public offering price per ordinary share in this offering and (ii) the closing price of our ordinary shares on the NOTC on September 22, 2015, which was NOK 145 per ordinary share, equivalent to a price of \$17.55 per share, assuming the exchange rate of NOK 8.2604 per U.S. dollar on September 22, 2015.

Also on September 22, 2015, our board of directors granted the number of stock options set forth below to each of our non-employee directors, representing the pro rata portion of their annual equity grant, which options will also become effective upon the pricing of this offering, with an exercise price equal to the higher of (i) the public offering price per ordinary share in this offering and (ii) the closing price of our ordinary shares on the NOTC on September 22, 2015, which was NOK 145 per ordinary share, equivalent to a price of \$17.55 per share, assuming the exchange rate of NOK 8.2604 per U.S. dollar on September 22, 2015.

- John H. Johnson—13,224 options

- Richard S. Kollender—9,918 options
- Mårten Steen—9,918 options
- Hilde H. Steineger—9,918 options
- Garheng Kong—9,385 options

Equity Compensation Plan

Our board of directors has adopted, and our shareholders have approved, the 2015 Equity Compensation Plan (the “2015 Plan”). The 2015 Plan provides for the grant of incentive stock options, within the meaning of Section 422 of the Internal Revenue Code, to our employees and any parent or subsidiary corporations’ employees, and for the grant of nonstatutory stock options, stock awards, and restricted stock units to our employees, directors and consultants and our parent or subsidiary corporations’ employees and consultants. The 2015 Plan is effective as of September 3, 2015.

Authorized Shares. A total of 1,081,818 shares of our common stock have been reserved for issuance pursuant to the 2015 Plan. The shares of our common stock that we have reserved for issuance pursuant to the 2015 Plan (the “Share Pool”), will be increased on the first day of each fiscal year beginning with the 2016 fiscal year, in an amount equal to four percent (4.0%) of the outstanding shares of our common stock on the last day of the immediately preceding fiscal year. After the completion of the offering, the maximum of 454,545 shares of our common stock may be subject to awards made under the 2015 Plan to any individual during a calendar year, subject to adjustment as provided in the 2015 Plan. The maximum number of shares that may be issued under the 2015 Plan as incentive stock options is 1,081,818. The Share Pool will be reduced on the date of grant, by one share of our common stock for each award under the 2015 Plan; provided that awards that are valued by reference to shares of our common stock but are required to be paid in cash pursuant to their terms will not reduce the Share Pool. If and to the extent options terminate, expire, or are canceled, forfeited, exchanged, or surrendered without having been exercised, or if any stock awards or awards of restricted stock units (including restricted stock received upon the exercise of options) are forfeited, the shares of our common stock subject to such awards will again be available for awards under the Share Pool. Notwithstanding the foregoing, the following shares of our common stock will not become available for issuance under the 2015 Plan: (i) shares tendered by individual grantees, or withheld by us, as full or partial payment to us upon the exercise of options granted under the 2015 Plan and (ii) shares withheld by, or otherwise remitted to us to satisfy an individual grantee’s tax withholding obligations upon the lapse of restrictions on stock awards, or the exercise of options granted under the 2015 Plan.

Plan Administration. Our compensation committee administers the 2015 Plan. Subject to the provisions of the 2015 Plan, our compensation committee has the power to determine the terms of the awards, including the exercise price, the number of shares of our common stock subject to each such award, the exercisability of the awards and the form of consideration, if any, payable upon exercise. To the maximum extent permitted by law, no member of our board or our compensation committee will be liable for any action taken or decision made in good faith relating to the 2015 Plan or any award granted thereunder.

Stock Options. The exercise price of options granted under the 2015 Plan may be equal to or greater than the fair market value of our common stock on the date of grant. The term of an option may not exceed ten years, except that the term of an incentive stock option granted to any employee who owns more than 10% of the voting power of all classes of our outstanding stock must not exceed five years and the exercise price must equal to at least 110% of the fair market value of our common stock on the grant date. After the termination of service of an employee, director or consultant for any reason other than death, disability or cause (as defined in the 2015 Plan), he or she may exercise the

vested portion of his or her option for 90 days. If termination is due to death (or death occurs within 90 days after the individual's termination date) or disability, the vested portion of the option will remain exercisable for one year. However, in no event may an option be exercised later than the expiration of its term. The entire option is forfeited upon a termination for Cause. In addition, if an employee, director or consultant has engaged in conduct that constitutes cause, any shares acquired upon exercise of an option for which we have not yet delivered the share certificates shall be automatically forfeited to us in exchange for payment of the exercise price paid for such shares.

Stock Awards. Stock awards may be granted under the 2015 Plan. Stock awards are grants of shares of our common stock that vest in accordance with terms and conditions established by the compensation committee. The compensation committee will determine the number of shares of granted as stock awards to any employee, director, or consultant and the consideration, if any, to be paid for such shares. The compensation committee may impose whatever conditions to vesting it determines to be appropriate (for example, the compensation committee may set restrictions based on the achievement of specific performance goals or continued service to us); provided, however, that the compensation committee, in its sole discretion, may accelerate the time at which any restrictions will lapse or be removed. Shares of our common stock subject to stock awards that do not vest are subject to forfeiture.

Restricted Stock Units. Restricted stock units may be granted under the 2015 Plan. Restricted stock units are bookkeeping entries representing an amount equal to the fair market value of one share of our common stock. The compensation committee determines the terms and conditions of restricted stock units, including the vesting criteria (which may include accomplishing specified performance criteria or continued service to us) and the form and timing of payment. The amount payable as a result of the vesting of a restricted stock unit will be distributed as soon as practicable following the vesting date and in no event later than the fifteenth date of the third calendar month of the year following the vesting date of the restricted stock unit (or as otherwise permitted under Section 409A of the Internal Revenue Code); provided, however, that an individual grantee may, if and to the extent permitted by our compensation committee, elect to defer payment of restricted stock units in a manner permitted by Section 409A of the Internal Revenue Code. Notwithstanding the foregoing, the compensation committee, in its sole discretion, may accelerate the time at which any restrictions will lapse or be removed.

Performance-Based Awards. Certain stock awards or restricted stock units granted under the 2015 Plan may be granted in a manner that should be deductible by us under Section 162(m) of the Internal Revenue Code. These awards, referred to as performance-based awards, will be determined based on the attainment of written performance goals approved by the compensation committee. The performance-based awards will be based upon one or more of the following objective criteria: (i) consolidated earnings before or after taxes (including earnings before interest, taxes, depreciation and amortization); (ii) net income; (iii) operating income; (iv) earnings per share; (v) return on shareholders' equity; (vi) attainment of strategic and operational initiatives; (vii) customer income; (viii) economic value-added models; (ix) maintenance or improvement of profit margins; (x) stock price (including total shareholder return), including, without limitation, as compared to one or more stock indices; (xi) market share; (xii) revenues, sales or net sales; (xiii) return on assets; (xiv) book value per share; (xv) expense management; (xvi) improvements in capital structure; (xvii) costs; and (xviii) cash flow. The foregoing criteria may relate to the company, one or more of our subsidiaries or one or more of our divisions or units, or any combination of the foregoing, and may be applied on an absolute basis and/or be relative to one or more peer group companies or indices, or any combination thereof, all as determined by the compensation committee. In addition, to the degree consistent with the Internal Revenue Code, the performance criteria may be calculated without regard to extraordinary, unusual and/or non-recurring items. With respect to performance-based awards, (i) the compensation committee will establish the objective performance goals applicable to a given period of service while the outcome

for that performance period is substantially uncertain and no later than 90 days after the commencement of that period of service (but in no event after 25% of that period of service has elapsed) and (ii) no awards will be granted to any participant for a given period of service until the compensation committee certifies that the objective performance goals (and any other material terms) applicable to that period have been satisfied.

Non-Transferability of Awards. Unless our compensation committee provides otherwise, the 2015 Plan generally does not allow for the transfer of awards and only the recipient of an award may exercise an award during his or her lifetime.

Certain Adjustments. In the event of certain changes in our capitalization, to prevent diminution or enlargement of the benefits or potential benefits available under the 2015 Plan, the compensation committee will adjust the number and class of shares that may be delivered under the 2015 Plan and/or the number, class and price per share of shares covered by each outstanding award, and the numerical share limits set forth in the 2015 Plan.

Change of Control. The 2015 Plan provides that in the event of a change of control, as defined in the 2015 Plan, where we are not the surviving corporation (or we survive only as a subsidiary of another corporation), unless our compensation committee determines otherwise, all outstanding awards will be assumed by, or replaced with comparable awards by, the surviving corporation in such change of control (or a parent or subsidiary of the surviving corporation). In the event the surviving corporation (or a parent or subsidiary of the surviving corporation) in such change of control does not assume or replace the outstanding awards with comparable awards, (i) we will provide written notice of such change of control to each individual grantee with outstanding awards; (ii) all outstanding options will automatically accelerate and become fully vested and exercisable; (iii) all outstanding stock awards will become vested and deliverable in accordance with the 2015 Plan; and (iv) all outstanding restricted stock units will become vested and deliverable in accordance with the 2015 Plan.

Notwithstanding the foregoing, if there is a change of control, our board may require that grantees surrender outstanding options in exchange for a payment of cash or stock equal to the amount by which the fair market value of the shares exceeds the exercise price or, after giving grantees an opportunity to exercise options, terminate all unexercised options, with such surrender or termination taking place as of the date of the change of control or such other date that our board specifies.

Amendment; Termination. Our board has the authority to amend, suspend or terminate the 2015 Plan provided such action does not impair the existing rights of any participant. The 2015 Plan automatically terminates in 2025, unless we terminate it sooner. We will obtain shareholder approval of any amendment to the 2015 Plan as required by applicable law or listing requirements.

Non-Employee Director Equity Compensation Plan

Our board of directors has adopted and our shareholders have approved, the Non-Employee Director Equity Compensation Plan (the Non-Employee Director Plan). The Non-Employee Director Plan provides for the grant of nonstatutory stock options, stock awards, and restricted stock units to our non-employee directors. The Non-Employee Director Plan is effective as of September 3, 2015.

Authorized Shares. A total of 345,454 shares of our common stock have been reserved for issuance pursuant to the Non-Employee Director Plan. The shares of our common stock that we have reserved for issuance pursuant to the Non-Employee Director Plan (the “Share Pool”), will be increased on the first day of each fiscal year beginning with the 2016 fiscal year, in an amount equal to one-half percent (0.5%) of the outstanding shares of our common stock on the last day of the immediately preceding fiscal year. The Share Pool will be reduced on the date of grant, by one share of our common stock for each award under the Non-Employee Director Plan; provided that awards that are valued by reference to shares of our common stock but are required to be paid in cash pursuant to

their terms will not reduce the Share Pool. If and to the extent options terminate, expire, or are canceled, forfeited, exchanged, or surrendered without having been exercised, or if any stock awards or awards of restricted stock units (including restricted stock received upon the exercise of options) are forfeited, the shares of our common stock subject to such awards will again be available for awards under the Share Pool. Notwithstanding the foregoing, shares tendered by individual grantees, or withheld by us, as full or partial payment to us upon the exercise of options will not become available for issuance again under the Non-Employee Director Plan.

Plan Administration. Our board administers the Non-Employee Director Plan. Subject to the provisions of the Non-Employee Director Plan, our board has the power to determine the terms of the awards, including the exercise price, the number of shares of our common stock subject to each such award, the exercisability of the awards and the form of consideration, if any, payable upon exercise. To the maximum extent permitted by law, no member of our board will be liable for any action taken or decision made in good faith relating to the Non-Employee Director Plan or any award granted thereunder.

Stock Options. The exercise price of options granted under the Non-Employee Director Plan may be equal to or greater than the fair market value of our common stock on the date of grant. The term of an option may not exceed ten years. After the termination of service of a non-employee director for any reason other than death, disability or cause (as defined in the Non-Employee Director Plan), he or she may exercise the vested portion of his or her option for 90 days. If termination is due to death (or death occurs within 90 days after the director's termination date) or disability, the vested portion of the option will remain exercisable for one year. However, in no event may an option be exercised later than the expiration of its term. The entire option is forfeited upon a termination for Cause. In addition, if a non-employee director has engaged in conduct that constitutes cause, any shares acquired upon exercise of an option for which we have not yet delivered the share certificates shall be automatically forfeited to us in exchange for payment of the exercise price paid for such shares.

Stock Awards. Stock awards may be granted under the Non-Employee Director Plan. Stock awards are grants of shares of our common stock that vest in accordance with terms and conditions established by the board. The board will determine the number of shares granted as stock awards to a non-employee director and the consideration, if any, to be paid for such shares. The board may impose whatever conditions to vesting it determines to be appropriate (for example, the board may set restrictions based on the achievement of specific performance goals or continued service to us); provided, however, that the board, in its sole discretion, may accelerate the time at which any restrictions will lapse or be removed. Shares of common stock subject to stock awards that do not vest are subject to forfeiture.

Restricted Stock Units. Restricted stock units may be granted under the Non-Employee Director Plan. Restricted stock units are bookkeeping entries representing an amount equal to the fair market value of one share of our common stock. The board determines the terms and conditions of restricted stock units, including the vesting criteria (which may include accomplishing specified performance criteria or continued service to us) and the form and timing of payment. The amount payable as a result of the vesting of a restricted stock unit will be distributed as soon as practicable following the vesting date and in no event later than the fifteenth date of the third calendar month of the year following the vesting date of the restricted stock unit (or as otherwise permitted under Section 409A of the Internal Revenue Code); provided, however, that an individual grantee may, if and to the extent permitted by our board, elect to defer payment of restricted stock units in a manner permitted by Section 409A of the Internal Revenue Code. Notwithstanding the foregoing, the board, in its sole discretion, may accelerate the time at which any restrictions will lapse or be removed.

Non-Transferability of Awards. Unless our board provides otherwise, the Non-Employee Director Plan generally does not allow for the transfer of awards and only the recipient of an award may exercise an award during his or her lifetime.

Certain Adjustments. In the event of certain changes in our capitalization, to prevent diminution or enlargement of the benefits or potential benefits available under the Non-Employee Director Plan, the board will adjust the number and class of shares that may be delivered under the Non-Employee Director Plan and/or the number, class and price per share of shares covered by each outstanding award.

Change of Control. The Non-Employee Director Plan provides that in the event of a change of control, as defined in the Non-Employee Director Plan, where we are not the surviving corporation (or we survive only as a subsidiary of another corporation), unless our board determines otherwise, all outstanding awards will be assumed by, or replaced with comparable awards by, the surviving corporation (or a parent or subsidiary of the surviving corporation). In the event the surviving corporation in such change of control (or a parent or subsidiary of the surviving corporation) does not assume or replace the outstanding awards with comparable awards, (i) we will provide written notice of such change of control to each individual grantee with outstanding awards; (ii) all outstanding options will automatically accelerate and become fully vested and exercisable; (iii) all outstanding stock awards will become vested and deliverable in accordance with the Non-Employee Director Plan; and (iv) all outstanding restricted stock units will become vested and deliverable in accordance with the Non-Employee Director Plan.

Notwithstanding the foregoing, if there is a change of control, our board may require that grantees surrender outstanding options in exchange for a payment of cash or stock equal to the amount by which the fair market value of the shares exceeds the exercise price and/or, after giving grantees an opportunity to exercise options, terminate all unexercised options, with such surrender or termination taking place as of the date of the change of control or such other date that our board specifies.

Amendment; Termination. Our board has the authority to amend, suspend or terminate the Non-Employee Director Plan provided such action does not impair the existing rights of any participant. The Non-Employee Director Plan automatically terminates in 2025, unless we terminate it sooner. We will obtain shareholder approval of any amendment to the Non-Employee Director Plan as required by applicable law or listing requirements.

PRINCIPAL SHAREHOLDERS

The following table presents information relating to the beneficial ownership of our ordinary shares as of October 14, 2015.

The number of ordinary shares beneficially owned by each entity, person, executive officer or director is determined in accordance with the rules of the SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. Under such rules, beneficial ownership includes any ordinary shares over which the individual has sole or shared voting power or investment power as well as any ordinary shares that the individual has the right to acquire within 60 days of October 14, 2015 through the exercise of any option or other right. Except as otherwise indicated, and subject to applicable community property laws, the persons named in the table have sole voting and investment power with respect to all ordinary shares held by that person.

Ordinary shares that a person has the right to acquire within 60 days of October 14, 2015 are deemed outstanding for purposes of computing the percentage ownership of the person holding such rights, but are not deemed outstanding for purposes of computing the percentage ownership of any other person, except with respect to the percentage ownership of all executive officers and directors as a group. The percentage of beneficial ownership of our ordinary shares prior to the offering is based on an aggregate of 18,705,382 shares outstanding as of October 14, 2015. As of October 14, 2015, we believe approximately 39% of our ordinary shares, are held by 48 record holders in the United States.

Certain of our existing shareholders that beneficially own more than 5% of our ordinary shares and their affiliates have indicated an interest in purchasing up to an aggregate of \$20.0 million of our ordinary shares in this offering at the initial public offering price per share. Based on the initial public offering price of \$10.00 per share, these entities would purchase up to an aggregate of 2,000,000 of the 2,500,000 shares in this offering based on these indications of interest. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters may determine to sell more, less or no shares in this offering to any of these entities, or any of these entities may determine to purchase more, less or no shares in this offering. The following table does not reflect any potential purchases by these shareholders or their affiliates. If any of our ordinary shares are purchased by these shareholders or their affiliates, the number of ordinary shares beneficially owned after this offering and the percentage of ordinary shares beneficially owned after this offering may differ from those set forth in the table below.

Unless otherwise indicated, the current business address for each Named Executive Officer is c/o Strongbridge Biopharma plc, 900 Northbrook Drive, Suite 200, Trevose, Pennsylvania 19053, United States.

Name of Beneficial Owner	Ordinary Shares Beneficially Owned Prior to the Offering		Ordinary Shares Beneficially Owned After the Offering	
	Number	Percent	Number	Percent
5% Shareholders				
TVM V Life Science Ventures GmbH & Co. KG ⁽¹⁾	2,354,890	12.6%	2,354,890	11.1%
HealthCap VI L.P. ⁽²⁾	2,226,091	11.9	2,226,091	10.5
RA Capital Healthcare Fund, LP ⁽³⁾	2,040,702	10.9	2,040,702	9.6
New Enterprise Associates ⁽⁴⁾	1,591,308	8.5	1,591,308	7.5
Eigil Stray Spetalen ⁽⁵⁾	1,119,807	6.0	1,119,807	5.3
Broadfin ⁽⁶⁾	1,105,056	5.9	1,105,056	5.2
Storebrand Funds ⁽⁷⁾	962,753	5.1	962,753	4.5
Named Executive Officers and Directors				
Matthew Pauls ⁽⁸⁾	95,829	*	95,829	*
Ruth Thieroff-Ekerdt, M.D. ⁽⁹⁾	4,679	*	4,679	*
Robert Lutz ⁽¹⁰⁾	76,638	*	76,638	*
H. Joseph Reiser ⁽¹¹⁾	735,705	3.9	735,705	3.4
John H. Johnson	—	—	—	—
Richard S. Kollender	—	—	—	—
Garheng Kong	—	—	—	—
Mårten Steen, M.D., Ph.D.	—	—	—	—
Hilde H. Steineger Ph.D.	—	—	—	—
<i>All Current Executive Officers and Directors as a Group (11 persons)⁽¹²⁾</i>	921,177	4.8	921,177	4.3

* Indicates beneficial ownership of less than 1% of the total outstanding ordinary shares.

(1) The address of TVM V Life Science Ventures GmbH & Co. KG is Ottostr. 4 80333 Munich, Germany

(2) The address of HealthCap VI L.P. is 18, Avenue d'Ouchy, 1006 Lausanne, Switzerland

(3) The address of RA Capital Healthcare Fund, LP is 20 Park Plaza, Suite 1200, Boston, MA 02116

(4) The address of New Enterprise Associates is 1954 Greenspring Drive, Suite 600, Timonium, MD 21093

(5) This number includes 665,262 shares held by Kristianro A/S. Mr. Spetalen, a former director of Cortendo AB, serves as the Chief Executive Officer and a director of Kristianro A/S and, as a result, may be deemed to have voting and investment power over the shares held by Kristianro A/S, in addition to the shares he holds directly.

(6) The address of Broadfin is 300 Park Avenue, 25th floor, New York, N.Y. 10022

(7) The address of Tredje AP-fonden is Vasagatan 7 9tr, 111 20 Stockholm, Sweden

(8) This number does not include 9,460 option shares that we expect will become exercisable during the 60 day period following October 14, 2015, beginning on the date that our shares begin trading on NASDAQ. See "Outstanding Equity Awards at December 31, 2014" for a description of the vesting terms of the option granted to Mr. Pauls in May 2015.

(9) This number does not include 1,136 option shares that we expect will become exercisable during the 60 day period following October 14, 2015, beginning on the date that our shares begin trading on NASDAQ. See "Outstanding Equity Awards at December 31, 2014" for a description of the vesting terms of the option granted to Dr. Thieroff-Ekerdt in May 2015.

(10) This number does not include 473 option shares that we expect will become exercisable during the 60 day period following October 14, 2015, beginning on the date that our shares begin trading on NASDAQ. See "Outstanding Equity Awards at December 31, 2014" for a description of the vesting terms of the options granted to Mr. Lutz in June 2015.

(11) Mr. Reiser is no longer an executive officer or director, but was a named executive officer of ours in 2014.

(12) This number does not include an aggregate of 2,272 option shares that we expect will become exercisable during the 60 day period following October 14, 2015, beginning on the date that our shares begin trading on NASDAQ. See "Outstanding Equity Awards at December 31, 2014" for a description of the vesting terms of the options granted to certain employees of the Company in May 2015.

To our knowledge, there have not been any significant changes in the ownership of our ordinary shares by our major shareholders over the past three years, except for the fact that TVM V Life Science Ventures GmbH & Co. KG, HealthCap VI, L.P., RA Capital Management, LLC, entities affiliated with New Enterprise Associates, Kristianro A/S, Broadfin and Storebrand Funds each became a substantial holder on or after May 2013, in connection with our private placements that closed May 2013, September 2013, December 1, 2014, February 10, 2015, and June 29 and 30, 2015.

RELATED PARTY TRANSACTIONS

The following is a description of transactions since January 1, 2012 to which we have been a party, in which the amount involved exceeded or will exceed \$120,000, and in which any of our executive officers, directors, promoters or holders of more than 5% of any class of our voting securities, or an affiliate or immediate family member thereof, had or will have a direct or indirect material interest, other than compensation, termination and change in control arrangements, which are described under “Executive Compensation.” We believe the terms obtained or consideration that we paid or received, as applicable, in connection with the transactions described below were comparable to terms available or the amounts that would be paid or received, as applicable, in arm’s-length transactions with unrelated third parties.

Certain of our existing shareholders that beneficially own more than 5% of our ordinary shares and their affiliates have indicated an interest in purchasing up to an aggregate of \$20.0 million of our ordinary shares in this offering at the initial public offering price per share. Based on the initial public offering price of \$10.00 per share, these entities would purchase up to an aggregate of 2,000,000 of the 2,500,000 shares in this offering based on these indications of interest. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters may determine to sell more, less or no shares in this offering to any of these entities, or any of these entities may determine to purchase more, less or no shares in this offering. The foregoing discussion and tables do not reflect any potential purchases by these entities or their affiliates.

On May 14, 2015, we entered into a Share Purchase Agreement to sell \$33.2 million of our shares in a private placement. Certain of our 5% shareholders participated in this transaction, including New Enterprise Associates, RA Capital Healthcare Fund, L.P. and HealthCap VI, LP, of which Mr. Steen, one of our directors, is a Partner. This transaction closed on June 29, 2015 and June 30, 2015 following shareholder approval at our AGM and other specified conditions. See “Summary—Recent Developments” for additional information regarding this transaction.

We may be required to make payments to Mr. Reiser in the event that BioPancreate or the major assets derived from the BioPancreate technology are sold to a third party. See the section titled “Executive Compensation Summary Compensation Table—Consulting Agreement with H. Joseph Reiser.”

In March 2012, following the completion of an equity financing, we repaid in full a bridge loan to our largest shareholder, Kristianro A/S (wholly owned by our Chairman at the time, Eigil Stray Spetalen), that had extended the loan during December 2011. The largest aggregate amount of principal outstanding during the life of the loan was approximately \$215,000. The amount of interest accrued for the entire period of the loan, which was paid in full March 2012, was approximately \$2,351. No amount remained outstanding at the end of 2012.

Policies and Procedures for Related Party Transactions

We intend to adopt a policy that our executive officers, directors, nominees for election as a director, beneficial owners of more than 5% of any class of our voting securities and any members of the immediate family of any of the foregoing persons are not permitted to enter into a related person transaction with us without the prior consent of our audit committee. Any request for us to enter into a transaction with an executive officer, director, nominee for election as a director, beneficial owner of more than 5% of any class of our voting securities or any member of the immediate family of any of the foregoing persons, in which the amount involved exceeds \$120,000 and such person would have a direct or indirect material interest, must first be presented to our audit committee for review, consideration and approval. In approving or rejecting any such proposal, our audit committee is to consider the material facts of the transaction, including, but not limited to, whether the transaction is on terms no less favorable than terms generally available to an unaffiliated third party under the same or similar circumstances and the extent of the related person’s interest in the transaction. All of the transactions described above were entered into prior to the adoption of such policy, but after presentation, consideration and approval by our board of directors.

DESCRIPTION OF SHARE CAPITAL AND ARTICLES OF ASSOCIATION

The following information is a summary of the material terms of our ordinary shares, nominal (*i.e.*, par) value \$0.01 per share, as specified in our Articles, that are currently in effect and which will be in effect upon completion of this offering.

Authorized Share Capital

Our authorized share capital is €40,000, divided into 40,000 deferred ordinary shares with a nominal value of €1.00 per share, and \$7,000,000, divided into 600,000,000 ordinary shares with a nominal value of \$0.01 per share and 100,000,000 preferred shares with a nominal value of \$0.01 per share.

The authorized and issued share capital includes 40,000 deferred ordinary shares, which are required in order to satisfy statutory minimum capital requirements of an Irish public limited company. The holders of the deferred ordinary shares are not entitled to receive any dividend or distribution, to attend, speak or vote at any general meeting, and have no effective rights to participate in the assets of our Company.

We may issue shares subject to the maximum authorized share capital contained in our Articles. The authorized share capital may be increased or reduced by a resolution approved by a simple majority of the votes cast at a general meeting of our shareholders, referred to under Irish law as an “ordinary resolution.” Our authorized share capital may be divided into shares of such nominal value as the resolution shall prescribe. As a matter of Irish law, the directors of a company may issue new ordinary or preferred shares without shareholder approval once authorized to do so by the memorandum and articles of association or by an ordinary resolution adopted by our shareholders at a general meeting. The authorization may be granted for a maximum period of five years, at which point it must be renewed by shareholders by an ordinary resolution. Accordingly, our Articles authorize our board of directors to issue new ordinary or preferred shares without shareholder approval for a period of five years from the date of the adoption of our Articles on September 9, 2015. The authority to issue preferred shares provides us with the flexibility to consider and respond to future business needs and opportunities as they arise from time to time, including in connection with capital raising, financing and acquisition transactions or opportunities.

Under our Articles, our board of directors is authorized to issue preferred shares on a non-pre-emptive basis, with discretion as to the terms attaching to the preferred shares, including as to voting, dividend and conversion rights and priority relative to other classes of shares with respect to dividends and upon a liquidation. As described in the preceding paragraph, this authority extends until five years from the date of the adoption of our Articles on September 9, 2015, at which time it will expire unless renewed by our shareholders.

Notwithstanding this authority, under the Irish Takeover Rules our board of directors would not be permitted to issue any of our shares, including preferred shares, during a period when an offer has been made for us or is believed to be imminent unless the issue is (i) approved by our shareholders at a general meeting; (ii) consented to by the Irish Takeover Panel on the basis it would not constitute action frustrating the offer; (iii) consented to by the Irish Takeover Panel and approved by the holders of more than 50% of our shares carrying voting rights; (iv) consented to by the Irish Takeover Panel in circumstances where a contract for the issue of the shares had been entered into prior to that period; or (v) consented to by the Irish Takeover Panel in circumstances where the issue of the shares was decided by our directors prior to that period and either action has been taken to implement the issuance (whether in part or in full) prior to such period or the issuance was otherwise in the ordinary course of business.

While we do not have any current specific plans, arrangements or understandings, written or oral, to issue any preferred shares for any purpose, we are continually evaluating our financial position and analyzing the possible benefits of issuing additional debt securities, equity securities, convertible

securities or a combination thereof in connection with, among other things: (i) repaying indebtedness; (ii) financing acquisitions; or (iii) strengthening our balance sheet. The availability of preferred shares gives us flexibility to respond to future capital raising, financing and acquisition needs and opportunities without the delay and expense associated with holding an extraordinary general meeting of our shareholders to obtain further shareholder approval.

The rights and restrictions to which the ordinary shares will be subject are prescribed in our memorandum of association and Articles. Our Articles permit our board of directors, without shareholder approval, to determine the terms of any preferred shares that we may issue. Our board of directors is authorized, without obtaining any vote or consent of the holders of any class or series of shares, unless expressly provided by the terms of that class or series of shares, to provide from time to time for the issuance of other classes or series of shares and to establish the characteristics of each class or series, including the number of shares, designations, relative voting rights, dividend rights, liquidation and other rights, redemption, repurchase or exchange rights and any other preferences and relative, participating, optional or other rights and limitations not inconsistent with applicable law.

Irish law does not recognize fractional shares held of record. Accordingly, our Articles do not provide for the issuance of fractional ordinary shares, and our official Irish share register will not reflect any fractional shares.

Preemption Rights, Share Warrants and Share Options

Under Irish law, unless otherwise authorized, when an Irish public limited company issues shares for cash to new shareholders, it is required first to offer those shares on the same or more favorable terms to existing shareholders of the company on a *pro rata* basis, commonly referred to as the statutory preemption right. However, we have opted out of these preemption rights in our Articles as permitted under Irish law. Because Irish law requires this opt-out to be renewed every five years by a special resolution of the shareholders, our Articles provide that this opt-out will lapse five years after the adoption of Strongbridge Biopharma plc's current Articles on September 9, 2015. A special resolution requires not less than 75% of the votes of our shareholders cast at a general meeting. If the opt-out is not renewed, shares issued for cash must be offered to pre-existing shareholders of Strongbridge *pro rata* to their existing shareholding before the shares can be issued to any new shareholders. The statutory preemption rights do not apply where shares are issued for non-cash consideration and do not apply to the issue of non-equity shares (that is, shares that have the right to participate only up to a specified amount in any income or capital distribution).

Issuance of Warrants and Options

Our Articles provide that, subject to any shareholder approval requirement under any laws, regulations or the rules of any stock exchange to which we are subject, our board of directors is authorized, from time to time, in its discretion, to grant such persons, for such periods and upon such terms as it deems advisable, options to purchase such number of shares of any class or classes or of any series of any class as our board of directors may deem advisable, and to cause warrants or other appropriate instruments evidencing such options to be issued. The Irish Companies Act provides that directors may issue share warrants or options without shareholder approval once authorized to do so by the articles of association or an ordinary resolution of shareholders. We will be subject to the rules of NASDAQ and the Irish Companies Act, which require shareholder approval of certain equity plan and share issuances. Our board of directors may issue shares upon exercise of warrants or options without shareholder approval or authorization, up to the relevant authorized share capital limit.

Dividends

Under Irish law, dividends and distributions may only be made from distributable reserves. Distributable reserves generally means accumulated realized profits less accumulated realized losses and includes reserves created by way of capital reduction. In addition, no distribution or dividend may be

made unless our net assets are equal to, or in excess of, the aggregate of our called up share capital plus undistributable reserves and the distribution does not reduce our net assets below such aggregate. Undistributable reserves include undenominated capital and the amount by which our accumulated unrealized profits, so far as not previously utilized by any capitalization, exceed our accumulated unrealized losses, so far as not previously written off in a reduction of capital approved by the Irish High Court without restriction, or a reorganization of capital.

The determination as to whether or not we have sufficient distributable reserves to fund a dividend must be made by reference to our “relevant financial statements.” The “relevant financial statements” will be either the last set of unconsolidated annual audited financial statements or other financial statements properly prepared in accordance with the Irish Companies Act, which give a “true and fair view” of our unconsolidated financial position and accord with accepted accounting practice.

The mechanism as to who declares a dividend and when a dividend shall become payable is governed by our Articles. Our Articles authorize our board of directors to declare dividends without shareholder approval to the extent they appear justified by profits lawfully available for distribution. Our board of directors may also recommend a dividend to be approved and declared by the shareholders at a general meeting. Our board of directors may direct that the payment be made by distribution of assets, shares or cash, and no dividend issued may exceed the amount recommended by our board of directors. Dividends may be declared and paid in the form of cash or non-cash assets and may be paid in dollars or any other currency.

Our board of directors may deduct from any dividend payable to any shareholder any amounts payable by such shareholder to us in relation to our ordinary shares.

Our board of directors may also authorize us to issue shares with preferred rights to participate in dividends we declare. The holders of preferred shares may, depending on their terms, rank senior to the ordinary shares in terms of dividend rights or be entitled to claim arrears of a declared dividend out of subsequently declared dividends in priority to ordinary shareholders.

For information about the Irish tax issues relating to dividend payments, please see the section of this prospectus titled “Taxation—Irish Tax Considerations—Irish Dividend Withholding Tax.”

Bonus Shares

Under our Articles, our board of directors may resolve to capitalize any amount credited to any reserve, including our undenominated capital, or credited to the profit and loss account, and use such amount for the issuance to shareholders of shares as fully paid bonus shares on the same basis of entitlement as would apply in respect of a dividend distribution.

Share Repurchases and Redemptions

Overview

Our Articles provide that any ordinary share that we have agreed to acquire shall be deemed to be a redeemable share. Accordingly, for Irish law purposes, the repurchase of ordinary shares by us may technically be effected as a redemption of those shares as described under “—Repurchases and Redemptions.” If our Articles did not contain such provision, repurchases by us would be subject to many of the same rules that apply to purchases of ordinary shares by subsidiaries described under “—Purchases by Subsidiaries,” including the shareholder approval requirements described below, and the requirement that any purchases on market be effected on a “recognized stock exchange,” which, for purposes of the Irish Companies Act, includes NASDAQ.

Except where otherwise noted, when we refer elsewhere in this prospectus to repurchasing or buying back our ordinary shares, we are referring to the redemption of our ordinary shares or the purchase of our ordinary shares by a subsidiary of us, in each case in accordance with our Articles and Irish law as described below.

Repurchases and Redemptions

Under Irish law, subject to the conditions summarized below, a company may issue redeemable shares and may only redeem them out of distributable reserves or the proceeds of a new issue of ordinary shares for that purpose. As described in “Dividend Policy,” we do not expect to have any distributable reserves for the foreseeable future. We may only issue redeemable shares if the nominal value of the issued share capital that is not redeemable is not less than 10% of the nominal value of our total issued share capital. All redeemable shares must also be fully paid and the terms of redemption of the shares must provide for payment on redemption. Redeemable shares may, upon redemption, be cancelled or held in treasury. Based on the provision of our Articles described above, shareholder approval will not be required to redeem our ordinary shares.

We may also be given an additional general authority to purchase our own shares on market, which would take effect on the same terms and be subject to the same conditions as applicable to purchases by our subsidiaries as described below.

Our board of directors may also issue preferred shares, which may be redeemed at the option of either us or the shareholder, depending on the terms of such preferred shares. Please see “—Authorized Share Capital” above for additional information on preferred shares.

Repurchased and redeemed shares may be cancelled or held as treasury shares. The nominal value of treasury shares held by us at any time must not exceed 10% of the nominal value of our issued share capital. We may not exercise any voting rights in respect of any shares held as treasury shares. Treasury shares may be cancelled by us or re-issued subject to certain conditions.

Purchases by Subsidiaries

Under Irish law, an Irish or non-Irish subsidiary may purchase our ordinary shares either on market or off market. For one of our subsidiaries to make purchases on market of our ordinary shares, the shareholders must provide general authorization for such purchase by way of ordinary resolution. However, as long as this general authority has been granted, no specific shareholder authority for a particular on market purchase by a subsidiary of our ordinary shares is required. For a purchase by a subsidiary off market, the proposed purchase contract must be authorized by special resolution of our shareholders before the contract is entered into. The person whose ordinary shares are to be bought back cannot vote in favor of the special resolution and the purchase contract must be on display or must be available for inspection by our shareholders at our registered office from the date of the notice of the meeting at which the resolution approving the contract is to be proposed.

In order for one of our subsidiaries to make an on market purchase of our ordinary shares, such shares must be purchased on a “recognized stock exchange.” NASDAQ is specified as a recognized stock exchange for this purpose by Irish law.

The number of ordinary shares held by our subsidiaries at any time will count as treasury shares and will be included in any calculation of the permitted treasury share threshold of 10% of the nominal value of our issued share capital. While a subsidiary holds any of our shares, it cannot exercise any voting rights in respect of those shares. The acquisition of our ordinary shares by a subsidiary must be funded out of distributable reserves of the subsidiary.

Lien on Shares, Calls on Shares and Forfeiture of Shares

Our Articles provide that we will have a first and paramount lien on every share that is not a fully paid share for all amounts payable at a fixed time or called in respect of that share. Subject to the terms of their allotment, directors may call for any unpaid amounts in respect of any shares to be paid, and if payment is not made, the shares may be forfeited. These provisions are customary in the articles of association of an Irish public company limited by shares such as our company and will only be applicable to shares that have not been fully paid.

Consolidation and Division; Subdivision

Under our Articles, we may, by ordinary resolution, consolidate and divide all or any of our share capital into shares of larger nominal value than our existing shares or subdivide our shares into smaller amounts than are fixed by our Articles.

Reduction of Share Capital

We may, by ordinary resolution, reduce our authorized share capital in any way. We also may, by special resolution and subject to confirmation by the Irish High Court, reduce or cancel our issued share capital in any manner permitted by the Irish Companies Act.

General Meetings of Shareholders

We are required to hold an annual general meeting within eighteen months of incorporation and at intervals of no more than fifteen months thereafter, provided that an annual general meeting is held in each calendar year following our first annual general meeting, no more than nine months after our fiscal year-end.

Our extraordinary general meetings may be convened by (i) our board of directors, (ii) on requisition of shareholders holding not less than 10% of our paid up share capital carrying voting rights or (iii) on requisition of our auditors. Extraordinary general meetings are generally held for the purposes of approving shareholder resolutions as may be required from time to time.

Notice of a general meeting must be given to all our shareholders and to our auditors. Our Articles provide that the maximum notice period is 60 days. The minimum notice periods are 21 days' notice in writing for an annual general meeting or an extraordinary general meeting to approve a special resolution and 14 days' notice in writing for any other extraordinary general meeting. General meetings may be called by shorter notice, but only with the consent of our auditors and all of our shareholders entitled to attend and vote thereat. Because of the 21-day and 14-day requirements described in this paragraph, our Articles include provisions reflecting these requirements of Irish law.

In the case of an extraordinary general meeting convened by our shareholders, the proposed purpose of the meeting must be set out in the requisition notice. Upon receipt of this requisition notice, our board of directors has 21 days to convene a meeting of our shareholders to vote on the matters set out in the requisition notice. This meeting must be held within two months of the receipt of the requisition notice. If our board of directors does not convene the meeting within such 21-day period, the requisitioning shareholders, or any of them representing more than one half of the total voting rights of all of them, may themselves convene a meeting, which meeting must be held within three months of the receipt of the requisition notice.

The only matters which must, as a matter of Irish company law, be transacted at an annual general meeting are the consideration of the Irish statutory financial statements, the report of the directors, the report of the auditors on those statements and that report and a review by the members of our affairs. If no resolution is made in respect of the reappointment of an auditor at an annual general meeting, the previous auditor will be deemed to have continued in office. Our Articles divide our board of directors into three classes, with members of each class being elected to staggered three-year terms. At each annual general meeting, directors will be elected for a full term of three years to succeed those directors of the relevant class whose terms are expiring. A nominee is elected to the board of directors by a plurality of the votes cast by the shareholders.

Holders of our ordinary shares are entitled to one vote for each share at all meetings at which directors are elected.

Our Articles provide for a minimum number of directors of two. In the event that an election results in only one director being elected, that director shall be elected and shall serve for a three-year

term, and the nominee receiving the next greatest number of votes in favour of their election shall hold office until his or her successor shall be elected.

If our directors become aware that our net assets are half or less of the amount of our called-up share capital, our directors must convene an extraordinary general meeting of our shareholders not later than 28 days from the date that they learn of this fact. This meeting must be convened for the purposes of considering whether any, and if so what, measures should be taken to address the situation.

Quorum for General Meetings

The presence, in person or by proxy, of the holders of our ordinary shares outstanding which entitle the holders to a majority of our voting power constitutes a quorum for the conduct of business. No business may take place at a general meeting if a quorum is not present in person or by proxy. Our board of directors has no authority to waive quorum requirements stipulated in our Articles. Abstentions and broker non-votes will be counted as present for purposes of determining whether there is a quorum in respect of the proposals.

Adjournment of Shareholder Meetings

Our Articles provide that if a quorum is not present, the meeting shall be adjourned and we shall notify shareholders in accordance with the usual notice requirements (as set out in “—Differences in Corporate Law Between Ireland and the State of Delaware—Record Date; Notice Provisions for Meetings of Shareholders”) in the event that such meeting is to be reconvened.

Voting

Under our Articles, each holder of our ordinary shares is entitled to one vote for each ordinary share that he or she holds as of the record date for the meeting. The holders of our deferred ordinary shares are not entitled to a vote. We may not exercise any voting rights in respect of any shares held as treasury shares. Any shares held by our subsidiaries will count as treasury shares for this purpose, and such subsidiaries cannot therefore exercise any voting rights in respect of those shares.

Irish law distinguishes between “ordinary business” and “special business.” Most business that is transacted at a general meeting is deemed “special” with the exception of declaring a dividend, the consideration of the statutory financial statements and the reports of the directors and auditors thereon, the review by the shareholders of the company’s affairs, the fixing of the remuneration of auditors and the election of directors, all of which are deemed to be “ordinary business.”

Our Articles provide that, except for the election of directors and where a greater majority is required by the Irish Companies Act (such as any matters that require special resolutions of the shareholders) as described below, any question, business or resolution proposed at any general meeting shall be decided by a simple majority of the votes cast.

All resolutions proposed at our general meetings will be decided on a poll. Every shareholder entitled to vote has one vote for each share held unless otherwise provided in our Articles. Voting rights may be exercised by shareholders registered in the share register as of the record date for the meeting or by a duly appointed proxy of such a registered shareholder, which proxy need not be a shareholder. Where interests in shares are held by a nominee trust company, this company may exercise the rights of the beneficial holders on their behalf as their proxy. All proxies must be appointed in accordance with our Articles. Our Articles permit the appointment of proxies by our shareholders to be notified to us electronically, when permitted by our directors.

In accordance with our Articles, our board of directors may from time to time authorize us to issue preference shares. These preferred shares may have such voting rights as may be specified in the terms of such preferred share. For example, they may carry more votes per share than ordinary shares

or may entitle their holders to a class vote on such matters as may be specified in the terms of the preferred shares. Treasury shares or our shares held by our subsidiaries will not be entitled to be voted at general meetings of shareholders.

Irish law requires special resolutions of our shareholders at a general meeting to approve certain matters. Examples of matters requiring special resolutions include:

- amending our objects or memorandum of association;
- amending our Articles;
- approving a change of our name;
- authorizing the entering into of a guarantee or provision of security in connection with a loan, quasi-loan or credit transaction to a director or connected person;
- opting out of preemption rights on the issuance of new shares;
- re-registering us from a public limited company to a private company;
- variation of class rights attaching to classes of shares (where our memorandum and articles of association do not provide otherwise);
- purchase of our ordinary shares off market;
- reduction of issued share capital;
- sanctioning a compromise or scheme of arrangement with creditors or shareholders;
- resolving that we be wound up by the Irish courts;
- resolving in favor of a shareholders' voluntary winding-up; and
- setting the re-issue price of treasury shares.

Action by Written Consent

Our Articles provide that shareholder resolutions are to be adopted by way of poll at meetings and shareholders are not permitted to pass resolutions by unanimous written consent.

Variation of Rights Attaching to a Class or Series of Shares

Under our Articles and the Irish Companies Act, any variation of class rights attaching to our issued shares must be approved by a special resolution of our shareholders of the affected class or with the consent in writing of the holders of 75% of all the votes of that class of shares.

Inspection of Books and Records

Under Irish law, shareholders have the right to (1) receive a copy of our Articles, (2) inspect and obtain copies of the minutes of general meetings and resolutions, (3) inspect and receive a copy of the register of shareholders, register of directors and secretaries, register of directors' interests and other statutory registers maintained by us, (4) receive copies of statutory financial statements (or summary financial statements, where applicable) and directors' and auditors' reports that have previously been sent to shareholders prior to an annual general meeting and (5) receive financial statements of any our subsidiaries that have previously been sent to shareholders prior to an annual general meeting for the preceding ten years. The auditors' report must be circulated to the shareholders with our financial statements prepared in accordance with Irish law 21 days before the annual general meeting and must be read to the shareholders at our annual general meeting.

Acquisitions

An Irish public limited company may be acquired in a number of ways, including:

- a court-approved scheme of arrangement under the Irish Companies Act. A scheme of arrangement with shareholders requires a court order from the Irish High Court and the approval of a majority in number representing 75% in value of the shareholders present and voting in person or by proxy at a meeting called to approve the scheme;
- through a tender or takeover offer by a third party for all of our shares. Where the holders of 80% or more of our ordinary shares have accepted an offer for their shares in our company, the remaining shareholders may also be statutorily required to transfer their shares. If the bidder does not exercise this “squeeze out” right, then the non-accepting shareholders also have a statutory right to require the bidder to acquire their shares on the same terms. If our shares were to be listed on the main securities market of the Irish Stock Exchange or another regulated stock exchange in the European Union, or EU, this threshold would be increased to 90%; and
- it is also possible for us to be acquired by way of a merger with an EU-incorporated company under the EU Cross-Border Mergers Directive 2005/56/EC. Such a merger must be approved by a special resolution. If we are being merged with another EU company under the EU Cross-Border Mergers Directive 2005/56/EC and the consideration payable to our shareholders is not all in the form of cash, our shareholders may be entitled to require their shares to be acquired at fair value.

Irish law does not generally require shareholder approval for a sale, lease or exchange of all or substantially all of a company’s property and assets. However, our Articles provide that an affirmative vote of the holders of a majority of the outstanding voting shares on the relevant record date is required to approve a sale, lease or exchange of all or substantially all of our property or assets.

Appraisal Rights

Generally, under Irish law, shareholders of an Irish company do not have dissenters’ or appraisal rights. Under the European Communities (Cross-Border Mergers) Regulations 2008, as amended, governing the merger of an Irish company limited by shares such as our company and a company incorporated in the European Economic Area, a shareholder (1) who voted against the special resolution approving the merger or (2) of a company in which 90% of the shares are held by the other party to the merger has the right to request in certain circumstances that the successor company acquire its shares for cash at a price determined in accordance with the share exchange ratio set out in the merger agreement.

Corporate Governance

Our Articles allocate authority over our day-to-day management to our board of directors. Our board of directors may then delegate our management to committees of our board of directors, consisting of one or more members of our board of directors, or to our executive officers, although our board of directors will remain responsible, as a matter of Irish law, for the proper management of our affairs. The proceedings of committees are governed by the Articles regulating the proceedings of directors. A vote at any committee meeting will be determined by a majority of votes of the members present.

Our board of directors has a standing audit committee, a compensation committee and a governance committee. We have also adopted corporate governance policies, including a code of conduct and an insider trading policy.

Upon the consummation of this offering, our corporate governance guidelines and general approach to corporate governance as reflected in our memorandum and articles of associations and our

internal policies and procedures will comply with applicable federal securities laws and regulations and NASDAQ requirements though the standards applicable to us as a foreign private issuer will generally be less restrictive than those applicable to U.S. companies. Although we are an Irish public limited company, we will not be subject to the listing rules of the Irish Stock Exchange or the listing rules of the U.K. Listing Authority and we are therefore not subject to, nor will we adopt, the U.K. Corporate Governance Code or any other non-statutory Irish or U.K. governance standards or guidelines. While there are many similarities and overlaps between the U.S. corporate governance standards applied by us and the U.K. Corporate Governance Code and other Irish/U.K. governance standards or guidelines, there are differences, in particular relating to the extent of the authorization to issue share capital and effect share repurchases that may be granted to our board and the criteria for determining the independence of our directors.

Directors

Number of Directors

The Irish Companies Act provides for a minimum of two directors. Our Articles provide for a minimum of two directors and a maximum of 13. Our shareholders may from time to time increase or reduce the maximum number, or increase the minimum number, of directors by ordinary resolution. Our board of directors determines the number of directors within the range of two to 13.

Election and Term of Office of Directors

Our Articles divide our board of directors into three classes, with members of each class being elected to staggered three-year terms. At each annual general meeting, directors will be elected for a full term of three years to succeed those directors of the relevant class whose terms are expiring. A nominee is elected to the board of directors by a plurality of the votes cast by shareholders.

Holders of our ordinary shares are entitled to one vote for each share at all meetings at which directors are elected.

Our Articles provide for a minimum number of directors of two. In the event that an election results in only one director being elected, that director shall be elected and shall serve for a three-year term, and the nominee receiving the next greatest number of votes in favour of their election shall hold office until his or her successor shall be elected.

Board Vacancies

Any vacancy on our board of directors, including a vacancy resulting from an increase in the number of directors or from the death, resignation, retirement, disqualification or removal of a director, shall be deemed a casual vacancy. Subject to the terms of any one or more classes or series of preferred shares, any casual vacancy shall only be filled by the decision of a majority of our board of directors then in office, provided that a quorum is present and provided that the appointment does not cause the number of directors to exceed any number fixed by or in accordance with our Articles as the maximum number of directors.

Any director of a class of directors elected to fill a vacancy resulting from an increase in the number of directors of such class shall hold office for the remaining term of that class. Any director elected to fill a vacancy not resulting from an increase in the number of directors shall have the same remaining term as that of his predecessor. A director retiring at a meeting shall retain office until the close or adjournment of the meeting.

Resignation, Removal and Disqualification of Directors

The Irish Companies Act provide that, notwithstanding anything contained in the articles of association of a company or in any agreement between that company and a director, the shareholders

may by an ordinary resolution remove a director from office before the expiration of his or her term. The power of removal is without prejudice to any claim for damages for breach of contract (e.g., employment contract) which the director may have against us in respect of his or her removal.

Our Articles also provide that the office of a director will also be vacated if the director is restricted or disqualified to act as a director under the Irish Companies Act; resigns his or her office by notice in writing to us or in writing offers to resign and the directors resolve to accept such offer; or is requested to resign in writing by not less than 75% of the other directors.

Indemnification Agreements

To the fullest extent permitted by Irish law, our Articles contain indemnification for the benefit of our directors, company secretary and executive officers. However, as to our directors and company secretary, this indemnity is limited by the Irish Companies Act, which prescribe that an advance commitment to indemnify only permits a company to pay the costs or discharge the liability of a director or company secretary where judgment is given in favor of the director or company secretary in any civil or criminal action in respect of such costs or liability, or where an Irish court grants relief because the director or company secretary acted honestly and reasonably and ought fairly to be excused. Any provision whereby an Irish company seeks to commit in advance to indemnify its directors or company secretary over and above the limitations imposed by the Irish Companies Act will be void, whether contained in its articles of association or any contract between the company and the director or company secretary. This restriction does not apply to our executive officers who are not directors, our company secretary or other persons who would be considered “officers” within the meaning of the Irish Companies Act.

We are permitted under our Articles and the Irish Companies Act to take out directors’ and officers’ liability insurance, as well as other types of insurance, for our directors, officers, employees and agents. In order to attract and retain qualified directors and officers, we expect to purchase and maintain customary directors’ and officers’ liability insurance and other types of comparable insurance.

We have entered, and intend to continue to enter, into separate indemnification agreements with our directors and executive officers, in addition to the indemnification provided for in our Articles. These agreements, among other things, provide that we will to the extent permitted under our Articles and the Irish Companies Act indemnify and provide expense advancement for our directors and executive officers for certain expenses, including attorneys’ fees, judgments, fines, and settlement amounts incurred by a director or executive officer in any action or proceeding arising out of their services as one of our directors or executive officers, or any of our subsidiaries or any other company or enterprise to which the person provides services at our request. At present, there is no pending litigation or proceeding involving any of our directors or executive officers as to which indemnification is required or permitted, and we are not aware of any threatened litigation or proceeding that may result in a claim for indemnification.

The indemnification provisions in our Articles may discourage shareholders from bringing a lawsuit against directors for breach of their fiduciary duties. They may also reduce the likelihood of derivative litigation against directors and officers, even though an action, if successful, might benefit us and our shareholders. A shareholder’s investment may be harmed to the extent we pay the costs of settlement and damage awards against directors and officers pursuant to these indemnification provisions. Insofar as indemnification for liabilities under the Securities Act may be permitted to directors, officers or persons controlling us pursuant to the foregoing provisions, we have been informed that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable. There is no pending litigation or proceeding naming any of our directors or officers as to which indemnification is being sought, nor are we aware of any pending or threatened litigation that may result in claims for indemnification by any director or officer.

Legal Name; Formation; Fiscal Year; Registered Office

Our fiscal year ends on December 31 and our registered address is Arthur Cox Building, Earlsfort Terrace, Dublin 2, Ireland.

Duration; Dissolution; Rights Upon Liquidation

The duration of our company will be unlimited. We may be dissolved and wound up at any time by way of a shareholders' voluntary winding up or a creditors' winding up. In the case of a shareholders' voluntary winding up, a special resolution of shareholders is required. Our company may also be dissolved by way of court order on the application of a creditor, or by the Companies Registration Office as an enforcement measure if we have failed to file certain returns. We may also be dissolved by the Director of Corporate Enforcement in Ireland where our affairs have been investigated by an inspector and it appears from the report or any information obtained by the Director of Corporate Enforcement that we should be wound up.

If our Articles contain no specific provisions in respect of a dissolution or winding up, then, subject to the priorities of any creditors, the assets will be distributed to our shareholders in proportion to the paid-up nominal value of the shares held. Our Articles provide that our ordinary shareholders are entitled to participate pro rata in a winding up, but their right to do so may be subject to the rights of any preference shareholders to participate under the terms of any series or class of preferred shares.

Uncertificated Shares

Holders of our ordinary shares will not have the right to require us to issue certificates for their shares.

No Sinking Fund

Our ordinary shares do not have sinking fund provisions.

Transfer and Registration of Shares

Our transfer agent will maintain the share register, registration in which will be determinative of ownership of our ordinary shares. A shareholder of our company who holds shares beneficially will not be the holder of record of such shares. Instead, the depository (for example, Cede & Co., as nominee for DTC) or other nominee will be the holder of record of those shares. Accordingly, a transfer of shares from a person who holds such shares beneficially to a person who also holds such shares beneficially through a depository or other nominee will not be registered in our official share register, as the depository or other nominee will remain the record holder of any such shares.

A written instrument of transfer is required under Irish law in order to register on our official share register any transfer of shares (1) from a person who holds such shares directly to any other person, (2) from a person who holds such shares beneficially but not directly to a person who holds such shares directly, or (3) from a person who holds such shares beneficially to another person who holds such shares beneficially where the transfer involves a change in the depository or other nominee that is the record owner of the transferred shares. An instrument of transfer is also required for a shareholder who directly holds shares to transfer those shares into or out of his or her own broker account. Such instruments of transfer may give rise to Irish stamp duty, which must be paid prior to registration of the transfer on our official Irish share register. However, a shareholder who directly holds shares outside of DTC may transfer those shares into DTC without giving rise to Irish stamp duty provided that (a) there is no change in beneficial ownership of the shares and (b) at the time of the transfer into or out of DTC there is no agreement in place for the sale of the shares by the beneficial owner to a third party.

Any transfer of our ordinary shares that is subject to Irish stamp duty will not be registered in the name of the buyer unless an instrument of transfer is duly stamped, the stamp duty thereon is paid by one of the parties and the instrument is provided to the transfer agent. We, in our absolute discretion and insofar as the Irish Companies Act or any other applicable law permits, may, or may procure that we or a subsidiary of our company shall, pay Irish stamp duty arising on a transfer of our ordinary shares on behalf of the transferee of such ordinary shares. If stamp duty resulting from the transfer of such ordinary shares which would otherwise be payable by the transferee is paid by our company or any subsidiary of our company on behalf of the transferee, then in those circumstances, we intend to, on our behalf or on behalf of our subsidiary, take one or a combination of the following actions: (1) require the transferee to pay to us or a subsidiary of our company the amount of such stamp duty and refuse to register such transfer until that amount is paid, (2) seek reimbursement of the stamp duty from the transferee, (3) set-off the stamp duty against any dividends payable to the transferee of those ordinary shares and (4) claim a first and permanent lien on the ordinary shares on which stamp duty has been paid by us or our subsidiary for the amount of stamp duty paid. Our lien shall extend to all dividends paid on those ordinary shares. Our Articles delegate authority to our company secretary (or his or her nominee) to execute an instrument of transfer on behalf of a transferring party.

In order to help ensure that the official share register is regularly updated to reflect trading of our ordinary shares occurring through normal electronic systems, we intend to regularly produce any required instruments of transfer in connection with any transactions for which we pay stamp duty, subject to the reimbursement and set-off rights described above. In the event that we notify one or both of the parties to a share transfer that we believe stamp duty is required to be paid in connection with the transfer and that we will not pay the stamp duty, the parties may either themselves arrange for the execution of the required instrument of transfer (and may request a form of instrument of transfer from us for this purpose) or request that we execute an instrument of transfer on behalf of the transferring party in a form determined by us. In either event, if the parties to the share transfer have the instrument of transfer duly stamped to the extent required and then provide it to our transfer agent, the buyer will be registered as the legal owner of the relevant shares on our official Irish share register, subject to the suspension right described below.

Our directors have general discretion to decline to register an instrument of transfer unless the transfer is in respect of one class of shares only. Our directors may suspend registration of transfers from time to time, not exceeding 30 days in aggregate each year.

Transfer of shares upon a listing

Our Articles provide that, with the exception of any listing or quotation on the Norwegian OTC, in the event of a listing or quotation of any class of share in our share capital or depository receipts representing any such class of share, on any stock exchange or securities market (a "Listing") any of our directors, and each of their expressly designated delegates (each an "Attorney") shall automatically, and without the requirement for any further action, be appointed the attorney of the holder(s) of any and all shares in the class or classes of shares in our capital, which is/are the subject of a Listing, in issue prior to a Listing (which, for avoidance of doubt, excludes any shares issued on the occurrence of, or in connection with, the Listing) with an irrevocable instruction to the Attorney to execute all or any forms of transfer and/or other documents that the Attorney, in his absolute discretion, considers necessary or expedient for the sole purpose of transferring such shares to a person appointed under contractual arrangements with us to hold our shares or rights or interests in our shares on a nominee basis.

Differences in Corporate Law Between Ireland and the State of Delaware

As a public limited company incorporated under the laws of Ireland, the rights of our shareholders are governed by applicable Irish law, including the Irish Companies Act, and not by the law of any U.S. state. As a result, our directors and shareholders are subject to different responsibilities, rights and privileges than are applicable to directors and shareholders of U.S. corporations. We have set below a summary of the differences between the provisions of the Irish Companies Act applicable to us and the Delaware General Corporation Law relating to stockholders' rights and protections. This summary is not intended to be a complete discussion of the respective rights and it is qualified in its entirety by reference to Irish law, Delaware law and our Articles. Before investing, you should consult your legal advisor regarding the impact of Irish corporate law on your specific circumstances and reasons for investing. The summary below does not include a description of rights or obligations under the U.S. federal securities laws or NASDAQ listing requirements. You are also urged to carefully read the relevant provisions of the Delaware General Corporation Law and the Irish Companies Act for a more complete understanding of the differences between Delaware and Irish law.

	<u>Delaware</u>	<u>Ireland</u>
<i>Authorized Capital</i>	<p>Under Delaware law, the board of directors without stockholder approval may approve the issuance of authorized but unissued shares of capital stock that are not otherwise committed for issuance.</p>	<p>Our authorised share capital may be increased or reduced, but not below the number of issued ordinary shares or preferred shares, as applicable, by a simple majority of the votes cast at a general meeting, referred to under Irish law as an "ordinary resolution."</p> <p>Under Irish law, the directors of a company may issue new ordinary or preferred shares without shareholder approval once authorized to do so by the memorandum and articles of association or by an ordinary resolution adopted by the shareholders at a general meeting. The authorization may be granted for a maximum period of five years, at which point it must be renewed by the shareholders by an ordinary resolution. Accordingly, our Articles authorize our board of directors to issue new preferred shares without shareholder approval for a period of five years from the date of the adoption of our Articles.</p> <p>The rights and restrictions to which our ordinary shares are subject is prescribed in our Articles. Our Articles entitle our board of directors, without shareholder approval, to determine the terms of any preferred shares issued. Preferred shares may be preferred as to dividends, rights on a winding up or voting in such manner as our directors may resolve. The preferred shares may also be redeemable at the option of the holder of the preferred shares or at our option, and may be convertible into or exchangeable for shares of any other class or classes, depending on the terms of such preferred shares.</p>

Reduction of Capital

Delaware

Under Delaware law, a corporation, by an affirmative vote of a majority of the board of directors, may reduce its capital by reducing or eliminating the capital represented by shares of capital stock which have been retired, by applying to an already authorized purchase redemption, conversion or exchange of outstanding shares of its capital stock some or all of the capital represented by shares being purchased, redeemed, converted or exchanged or any capital that has not been allocated to any particular class of capital stock or by transferring to surplus capital some or all of the capital not represented by any particular class of its capital stock or the capital associated with certain issued shares of its par value capital stock. No reduction of capital may be made unless the assets of the corporation remaining after the reduction are sufficient to pay any debts for which payment has not otherwise been otherwise provided.

Ireland

A company may, by ordinary resolution, reduce its authorized share capital in any way. A company also may, by special resolution and subject to confirmation by the Irish High Court, reduce or cancel its issued share capital in any way permitted by the Irish Companies Act.

Preemption Rights; Consideration for Shares

Under Delaware law, unless otherwise provided in a corporation's certificate of incorporation or any amendment thereto, or in the resolution or resolutions providing for the issue of such shares adopted by the board of directors pursuant to authority expressly vested in it by the provisions of its certificate of incorporation, a stockholder does not, by operation of law, possess preemptive rights to subscribe to additional issuances of the corporation's capital stock.

Under Irish law, unless otherwise authorized, when an Irish public limited company issues shares for cash to new shareholders, it is required first to offer those shares on the same or more favorable terms to existing shareholders of the company on a *pro rata* basis, commonly referred to as the statutory preemption right. However, we have opted out of these preemption rights in our Articles as permitted under Irish law. Because Irish law requires this opt-out to be renewed every five years by a special resolution of the shareholders, our Articles provide that this opt-out will lapse five years after the adoption of our current Articles on September 9, 2015. A special resolution requires not less than 75% of the votes of our shareholders cast at a general meeting. If this opt-out is not renewed, shares issued for cash must be offered to our pre-existing shareholders *pro rata* to their existing shareholding before the shares can be issued to any new shareholders. Statutory preemption rights do not apply (1) where shares are issued for non-cash consideration, such as in a share-for-share acquisition, (2) to the issue of non-equity shares, that is, shares that have the right to participate only up to a specified amount in any income or capital distribution, or (3) where shares are issued pursuant to an employee share option or similar equity plan.

Delaware

Dividends, Distributions, Repurchases and Redemptions

Dividends and Distributions

Under Delaware law, unless otherwise provided in a corporation's certificate of incorporation, directors may declare and pay dividends upon its capital stock either (1) out of its surplus or (2) if the corporation does not have surplus, out of its net profits for the fiscal year in which the dividend is declared or the preceding fiscal year.

The excess, if any, at any given time, of the net assets of the corporation over the amount so determined to be capital is surplus. Net assets means the amount by which total assets exceed total liabilities.

Dividends may be paid in cash, in property, or in shares of the corporation's capital stock.

Ireland

Under Irish law, a company is prohibited from allotting shares without consideration. Accordingly, at least the nominal value of the shares issued underlying any restricted share award, restricted share unit, performance share awards, bonus shares or any other share-based grants must be paid pursuant to the Irish Companies Act.

Dividends and Distributions

Under Irish law, dividends and distributions may only be made from distributable reserves. Distributable reserves generally means accumulated realized profits less accumulated realized losses and includes reserves created by way of capital reduction. In addition, no distribution or dividend may be made unless the net assets of a company are equal to, or in excess of, the aggregate of that company's called up share capital plus undistributable reserves and the distribution does not reduce that company's net assets below such aggregate. Undistributable reserves include undenominated capital and the amount by which a company's accumulated unrealized profits, so far as not previously utilized by any capitalization, exceed that company's accumulated unrealized losses, so far as not previously written off in a reduction of capital approved by the Irish High Court without restriction, or a reorganization of capital.

The determination as to whether or not a company has sufficient distributable reserves to fund a dividend must be made by reference to the "relevant financial statements" of that company. The "relevant financial statements" will be either the last set of unconsolidated annual audited financial statements or other financial statements properly prepared in accordance with the Irish Companies Act, which give a "true and fair view" of a company's unconsolidated financial position and accord with accepted accounting practice. The relevant financial statements must be filed in the Companies Registration Office (the official public registry for companies in Ireland).

Dividends may be declared and paid in the form of cash or non-cash assets and may be paid in dollars or any other currency.

Delaware

Share Repurchases and Redemptions

Under Delaware law, any stock of any class or series may be made subject to redemption by the corporation at its option or at the option of the holders of such stock or upon the happening of a specified event; provided however, that immediately following any such redemption the corporation must have outstanding one or more shares of one or more classes or series of stock, which share, or shares together, have full voting powers.

Any stock which may be made redeemable may be redeemed for cash, property or rights, including securities of the same or another corporation, at such time or times, price or prices, or rate or rates, and with such adjustments, as stated in the certificate of incorporation or in the resolution or resolutions providing for the issue of such stock adopted by the board of directors.

Every corporation may purchase, redeem, receive, take or otherwise acquire, own and hold, sell, lend, exchange, transfer or otherwise dispose of, pledge, use and otherwise deal in and with its own shares; provided, however, that no corporation may: (1) purchase or redeem its own shares of capital stock for cash or other property when the capital of the corporation is impaired or when such purchase or redemption would cause any impairment of the capital of the corporation, except that a corporation other than a non-stock corporation may purchase or redeem out of capital any of its own shares which are entitled upon any distribution of its assets, whether by dividend or in liquidation, to a preference over another class or series of its shares, or, if no shares entitled to such a preference are outstanding, any of its own shares, if such shares will be retired upon their acquisition and the capital of the corporation reduced; (2) purchase, for more than the price at which they may then be redeemed, any of its shares which are redeemable at the option of the corporation; or (3) redeem any of its shares, unless their redemption is authorized by Delaware law and then only in accordance with its certificate of incorporation.

Ireland

Share Repurchases and Redemptions

Our Articles provide that any ordinary share that we agree to acquire shall be deemed to be a redeemable share. Accordingly, for purposes of Irish law, the repurchase of ordinary shares by us may technically be effected as a redemption.

Under Irish law, we may issue redeemable shares and redeem them out of distributable reserves or the proceeds of a new issue of shares for that purpose. We may only issue redeemable shares if the nominal value of the issued share capital that is not redeemable is not less than 10% of the nominal value of our total issued share capital. All redeemable shares must also be fully-paid and the terms of redemption of the shares must provide for payment on redemption.

We may also be given authority to purchase our shares on a recognized stock exchange such as the NASDAQ or off market purchases with such authority to be given by our shareholders at a general meeting, which would take effect on the same terms and be subject to the same conditions as applicable to purchases by our subsidiaries.

Our board of directors may also issue preferred shares, which may be redeemed at the option of either us or the shareholder, depending on the terms of such preferred shares.

Repurchased and redeemed shares may be cancelled or held as treasury shares. The nominal value of treasury shares held by us at any time must not exceed 10% of the nominal value of our issued share capital. We may not exercise any voting rights in respect of any shares held as treasury shares. Treasury shares may be canceled by us or re-issued subject to certain conditions.

Delaware

Purchases by Subsidiaries

Under Delaware law, shares of a corporation's capital stock may be acquired by subsidiaries of that corporation without stockholder approval. Such capital stock owned by a majority owned subsidiary are neither entitled to vote nor counted as outstanding for quorum purposes.

Ireland

Purchases by Subsidiaries

Under Irish law, a company's subsidiaries may purchase shares of that company either on market on a recognized stock exchange such as NASDAQ or off market.

For one of our subsidiaries to make on market purchases of our ordinary shares, our shareholders must provide general authorization for such purchase by way of ordinary resolution. However, as long as this general authority has been granted, no specific shareholder authority for a particular on market purchase by a subsidiary of our ordinary shares is required. For a purchase by a subsidiary off market, the proposed purchase contract must be authorized by special resolution of our shareholders before the contract is entered into. The person whose ordinary shares are to be bought back cannot vote in favor of the special resolution and the purchase contract must be on display or must be available for inspection by our shareholders at our registered office from the date of the notice of the meeting at which the resolution approving the contract is to be proposed.

The number of shares held by our subsidiaries at any time will count as treasury shares and will be included in any calculation of the permitted treasury share threshold of 10% of the nominal value of our issued share capital. While a subsidiary holds our shares, such subsidiary cannot exercise any voting rights in respect of those shares. The acquisition of our ordinary shares by a subsidiary must be funded out of distributable reserves of the subsidiary.

Election of Directors

Delaware

Under Delaware law, a corporation must have at least one director. The number of directors of a corporation is fixed by, or in the manner provided in, the bylaws, unless the certificate of incorporation fixes the number of directors, in which case a change in the number of directors must be made by amendment of the certificate of incorporation. Delaware law does not contain specific provisions requiring a majority of independent directors.

Ireland

Our Articles divide our board of directors into three classes, with members of each class being elected to staggered three-year terms. At each annual general meeting, directors will be elected for a full term of three years to succeed those directors of the relevant class whose terms are expiring. A nominee is elected to the board of directors by a plurality of the votes cast by shareholders.

Holders of our ordinary shares are entitled to one vote for each share at all meetings at which directors are elected.

Our Articles provide for a minimum number of directors of two. In the event that an election results in only one director being elected, that director shall be elected and shall serve for a three-year term, and the nominee receiving the next greatest number of votes in favour of their election shall hold office until his or her successor shall be elected.

Registration, Removal and Disqualification of Directors

Under Delaware law, unless otherwise provided in the certificate of incorporation, directors may be removed from office, with or without cause, by a majority stockholder vote, except: (1) in the case of a corporation whose board of directors is classified, stockholders may effect such removal only for cause; and (2) in the case of a corporation having cumulative voting, if less than the entire board of directors is to be removed, no director can be removed without cause if the votes cast against such director's removal would be sufficient to elect such director if then cumulatively voted at an election of the entire board of directors, or, if there are classes of directors, at an election of the class of directors of which such director is a part.

Under the Irish Companies Act and notwithstanding anything contained in our Articles or in any agreement between us and a director, the shareholders may, by an ordinary resolution, remove a director from office before the expiration of his or her term at a meeting held on no less than 28 days notice and at which the director is entitled to be heard. Because of this provision of the Irish Companies Act, our Articles provide that we may, by ordinary resolution, remove any director before the expiration of his period of office notwithstanding anything in any agreement between us and the removed director. The power of removal is without prejudice to any claim for damages for breach of contract, *e.g.*, employment contract, that the director may have against us in respect of his or her removal. Our Articles also provide that the office of a director will also be vacated if the director is restricted or disqualified to act as a director under the Acts; resigns his or her office by notice in writing to us or in writing offers to resign and the directors resolve to accept such offer; or is requested to resign in writing by not less than 75% of the other directors.

Delaware

Quorum of the Board of Directors

The quorum necessary for transaction of business by the board of directors shall consist of a majority of the total number of directors unless the certificate of incorporation or bylaws require a greater number.

Duties of Directors

Under Delaware law, a company's directors are charged with fiduciary duties of care and loyalty. The duty of care requires that directors act in an informed and deliberate manner and inform themselves, prior to making a business decision, of all relevant material information reasonably available to them. The duty of care also requires that directors exercise care in overseeing and investigating the conduct of corporate employees. The duty of loyalty may be summarized as the duty to act in good faith, not out of self-interest, and in a manner which the director reasonably believes to be in the best interests of the corporation and its stockholders. A party challenging the propriety of a decision of a board of directors bears the burden of rebutting the applicability of the presumptions afforded to directors by the "business judgment rule." If the presumption is not rebutted, the business judgment rule attaches to protect the directors and their decisions. Notwithstanding the foregoing, Delaware courts may subject directors' conduct to enhanced scrutiny in respect of defensive actions taken in response to a threat to corporate control and approval of a transaction resulting in a sale of control of the corporation.

Ireland

The quorum necessary for transaction of business by our board of directors may be a majority of the directors in office at the time when the meeting is convened.

Our directors have certain statutory and fiduciary duties. All of our directors have equal and overall responsibility for the management of our company, although directors who also serve as employees will have additional responsibilities and duties arising under their employment agreements and it is likely that more will be expected of them in compliance with their duties than non-executive directors. The principal fiduciary duties of directors are stated in section 228 of the Irish Companies Act and include the duties of good faith and exercising due care and skill. Directors' statutory duties also include ensuring the maintenance of proper books of account, having annual accounts prepared, having an annual audit performed and the duty to maintain certain registers and make certain filings as well as disclosure of personal interests. For public limited companies like us, directors are under a specific duty to ensure that the secretary is a person with the requisite knowledge and experience to discharge the role.

Under Irish law, a director is entitled to rely on information, opinions, reports or statements, including financial statements and other financial data, prepared or presented by (1) other directors, officers or employees of the company whom the director reasonably believes to be reliable and competent in the matters prepared or presented, (2) legal counsel, public accountants or other persons as to matters the director reasonably believes are within their professional or expert competence, or (3) a committee of the board of which the director does not serve as to matters within its designated authority, which committee the director reasonably believes to merit confidence.

Conflicts of Interest of Directors

Delaware

Under Delaware law, a contract or transaction in which a director has an interest will not be voidable solely for this reason if (1) the material facts with respect to such interested director's relationship or interest in the contract or transaction are disclosed or are known to the board of directors, and the board of directors in good faith authorizes the transaction by the affirmative vote of a majority of the disinterested directors, (2) the material facts with respect to such interested director's relationship or interest in the contract or transaction are disclosed or are known to the stockholders entitled to vote on such transaction, and the transaction is specifically approved in good faith by vote of the majority of shares entitled to vote thereon, or (3) the contract or transaction is fair to the corporation as of the time it is authorized, approved or ratified. The mere fact that an interested director is present and voting on a transaction in which he or she is interested will not itself make the transaction void. Under Delaware law, an interested director could be held liable for a transaction in which such director derived an improper personal benefit.

Ireland

As a matter of Irish law, a director is under a general fiduciary duty to avoid conflicts of interest. Under Irish law, directors who have a personal interest in a contract or proposed contract with a company are required to declare the nature of their interest at a meeting of the directors of that company. A company is required to maintain a register of declared interests, which must be available for shareholder inspection.

Our Articles provide that a director must declare any interest he or she may have in a contract with us at a meeting of our board of directors in accordance with the Irish Companies Act.

Our Articles provide that a director may vote in respect of any contract, appointment or arrangement in which he is interested, and he shall be counted in the quorum present at the meeting.

Under our Articles, a director may be a director of, other officer of, or otherwise interested in, any company promoted by us or in which we are interested, and such director will not be accountable to us for any compensation or other benefit received from such employment or other interest. Our Articles further provide that (1) no director will be prevented from contracting with us because of his or her position as a director, (2) any contract entered into between a director and us will not be subject to avoidance, and (3) no director will be liable to account to us for any profits realized by virtue of any contract between such director and us because the director holds such office or the fiduciary relationship established thereby.

Indemnification of Officers and Directors

Delaware

Delaware law permits a corporation to indemnify, and to advance expenses to, officers and directors for actions taken in good faith and in a manner they reasonably believed to be in, or not opposed to, the best interests of the corporation, and with respect to any criminal action that they had no reasonable cause to believe was unlawful.

Ireland

Irish law permits indemnification for the benefit of a company's directors and executive officers. However, as to directors and company secretary, this indemnity is limited by the Irish Companies Act, which prescribes that an advance commitment to indemnify only permits a company to pay the costs or discharge the liability of a director or company secretary where judgment is given in favor of the director or company secretary in any civil or criminal action in respect of such costs or liability, or where an Irish court grants relief because the director or company secretary acted honestly and reasonably and ought fairly to be excused. Any provision whereby an Irish company seeks to commit in advance to indemnify its directors or company secretary over and above the limitations imposed by the Irish Companies Act will be void, whether contained in its articles of association or any contract between the company and the director or company secretary. This restriction does not apply to executive officers who are not directors, the company secretary or other persons who are considered "officers" within the meaning of the Irish Companies Act.

Our Articles also contain indemnification and expense advancement provisions for current or former executives who are not directors or our company secretary.

Our directors may, on a case-by-case basis, decide at their discretion that it is in our best interests to indemnify an individual director from any liability arising from his or her position as a director of us. However, this discretion must be exercised *bona fide* in our best interests as a whole. Any such indemnity will be limited in the manner described in the foregoing paragraphs.

We are permitted under our Articles and the Irish Companies Act to take out directors' and officers' liability insurance, as well as other types of insurance, for our directors, officers, employees and agents. In order to attract and retain qualified directors and officers, we expect to purchase and maintain customary directors' and officers' liability insurance and other types of comparable insurance.

Delaware

Ireland

We have entered, and intend to continue to enter, into separate indemnification agreements with our directors and executive officers, in addition to the indemnification provided for in our Articles. These agreements, among other things, provide that we will to the extent permitted under our Articles and the Irish Companies Act indemnify and provide expense advancement for our directors and executive officers for certain expenses, including attorneys' fees, judgments, fines, and settlement amounts incurred by a director or executive officer in any action or proceeding arising out of their services as one of our directors or executive officers, or any of our subsidiaries or any other company or enterprise to which the person provides services at our request. At present, there is no pending litigation or proceeding involving any of our directors or executive officers as to which indemnification is required or permitted, and we are not aware of any threatened litigation or proceeding that may result in a claim for indemnification. The indemnification provisions in our Articles may discourage shareholders from bringing a lawsuit against directors for breach of their fiduciary duties. They may also reduce the likelihood of derivative litigation against directors and officers, even though an action, if successful, might benefit us and our shareholders. A shareholder's investment may be harmed to the extent we pay the costs of settlement and damage awards against directors and officers pursuant to these indemnification provisions. Insofar as indemnification for liabilities under the Securities Act may be permitted to directors, officers or persons controlling us pursuant to the foregoing provisions, we have been informed that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable. There is no pending litigation or proceeding naming any of our directors or officers as to which indemnification is being sought, nor are we aware of any pending or threatened litigation that may result in claims for indemnification by any director or officer.

Limitation on Director Liability

Delaware

Under Delaware law, a corporation may include in its certificate of incorporation a provision that limits or eliminates the personal liability of directors to the corporation and its stockholders for monetary damages for a breach of fiduciary duty as a director. However, a corporation may not limit or eliminate the personal liability of a director for: (1) any breach of the director's duty of loyalty to the corporation or its stockholders; (2) acts or omissions in bad faith or which involve intentional misconduct or a knowing violation of law; (3) intentional or negligent payments of unlawful dividends or unlawful share purchases or redemptions; or (4) any transaction in which the director derives an improper personal benefit.

Ireland

Under Irish law, a company may not exempt its directors from liability for negligence or a breach of duty. However, where a breach of duty has been established, directors may be statutorily exempted by an Irish court from personal liability for negligence or breach of duty if, among other things, the court determines that they have acted honestly and reasonably, and that they may fairly be excused as a result.

Under Irish law, shareholders may not agree to exempt a director or officer from any claim or right of action the shareholder may have, whether individually or in the right of a company, on account of any action taken or the failure to take any action in the performance of his or her duties to that company.

General Meetings of Shareholders

Under Delaware law, an annual meeting of stockholders is required. Any stockholder or director may apply to the Delaware Chancery Court for an order for a corporation to hold an annual meeting if the corporation has failed to hold an annual meeting for a period of 13 months after its last annual meeting.

We are required to hold an annual general meeting within eighteen months of incorporation and at intervals of no more than fifteen months thereafter, provided that an annual general meeting is held in each calendar year following our first annual general meeting, no more than nine months after our fiscal year-end.

Our extraordinary general meetings may be convened by (1) our board of directors, (2) on requisition of shareholders holding not less than 10% of our paid up share capital carrying voting rights or (3) on requisition of our auditors. Extraordinary general meetings are generally held for the purposes of approving shareholder resolutions as may be required from time to time.

Notice of a general meeting must be given to all our shareholders and to our auditors. Our Articles provide that the maximum notice period is 60 days. The minimum notice periods are 21 days' notice in writing for an annual general meeting or an extraordinary general meeting to approve a special resolution and 14 days' notice in writing for any other extraordinary general meeting. General meetings may be called by shorter notice, but only with the consent of our auditors and all of our shareholders entitled to attend and vote thereat. Because of the 21-day and 14-day requirements described in this paragraph, our Articles include provisions reflecting these requirements of Irish law.

Delaware

Ireland

In the case of an extraordinary general meeting convened by our shareholders, the proposed purpose of the meeting must be set out in the requisition notice. The requisition notice can contain any resolution. Upon receipt of this requisition notice, our board of directors has 21 days to convene a meeting of our shareholders to vote on the matters set out in the requisition notice. This meeting must be held within two months of the receipt of the requisition notice. If our board of directors does not convene the meeting within such 21-day period, the requisitioning shareholders, or any of them representing more than one half of the total voting rights of all of them, may themselves convene a meeting, which meeting must be held within three months of the receipt of the requisition notice.

The only matters which must, as a matter of Irish company law, be transacted at an annual general meeting are the consideration of the Irish statutory financial statements, the report of the directors, the report of the auditors on these statements and that report and a review by the members of our affairs. If no resolution is made in respect of the reappointment of an auditor at an annual general meeting, the previous auditor will be deemed to have continued in office. Our Articles divide our board of directors into three classes, with members of each class being elected to staggered three-year terms. At each annual general meeting, directors will be elected for a full term of three years to succeed those directors of the relevant class whose terms are expiring. A nominee is elected to the board of directors by a plurality of the votes cast by shareholders.

Holders of our ordinary shares are entitled to one vote for each share at all meetings at which directors are elected.

Our Articles provide for a minimum number of directors of two. In the event that an election results in only one director being elected, that director shall be elected and shall serve for a three-year term, and the nominee receiving the next greatest number of votes in favour of their election shall hold office until his or her successor shall be elected.

Delaware

Ireland

Advance Notice Provisions

As may be set by the corporation's bylaws.

If our directors become aware that our net assets are half or less of the amount of our called-up share capital, our directors must convene an extraordinary general meeting of our shareholders not later than 28 days from the date that they learn of this fact. This meeting must be convened for the purposes of considering whether any, and if so what, measures should be taken to address the situation.

Our Articles provide that (a) with respect to an annual general meeting of shareholders, nominations of persons for election to the board of directors and the proposal of business to be considered by shareholders may be made only pursuant to our notice of meeting; by our board of directors; or by a shareholder who is entitled to vote at the meeting and who has complied with the advance notice procedures provided for our Articles, and (b) with respect to an extraordinary general meeting of shareholders, nominations of persons for election to our board of directors and the proposal of business to be considered by shareholders may be made only pursuant to our notice of meeting; by our board of directors; by any shareholders pursuant to the valid exercise of the power granted under the Irish Companies Act; or by a shareholder who is entitled to vote at the meeting and who has complied with the advance notice procedures provided for in our Articles.

Delaware

Ireland

In order to comply with the advance notice procedures of our Articles, a shareholder must give written notice to our Secretary on a timely basis. To be timely for an annual general meeting, notice must be delivered, or mailed and received, at least 120 days in advance of the first anniversary of the date that we released the proxy statement for the preceding year's annual general meeting, subject to certain exceptions. To be timely for an extraordinary general meeting, notice must be delivered, or mailed and received, by the later of (1) 120 days in advance of the meeting or (2) the date that is 10 days after the date of the first public announcement of the date of the meeting. For nominations to our board of directors, the notice must include all information about the director nominee that is required to be disclosed by SEC rules regarding the solicitation of proxies for the election of directors and such other information as we may reasonably require to determine the eligibility of the proposed nominee.

For other business that a shareholder proposes to bring before the meeting, the notice must include a brief description of the business, the reasons for proposing the business at the meeting and a discussion of any material interest of the shareholder in the business.

Whether the notice relates to a nomination to the board of directors or to other business to be proposed at the meeting, the notice also must include information about the shareholder and the shareholder's holdings of our shares.

In addition, the Irish Companies Act provides that shareholders holding not less than 10% of the total voting rights may call an extraordinary general meeting for the purpose of considering director nominations or other proposals, as described below under "—Special/ Extraordinary Shareholder Meetings." The chairman of the meeting may refuse to transact any business or may disregard nomination of any person if a shareholder fails to comply with the foregoing procedures.

Proxy

Under Delaware law, at any meeting of stockholders, a stockholder may designate another person to act for such stockholder by proxy, but no such proxy may be voted or acted upon after three years from its date, unless the proxy provides for a longer period.

Under the Irish Companies Act, at any meeting of shareholders, a shareholder may designate another person to attend, speak and vote at the meeting on their behalf by proxy, but no such proxy shall be voted or acted upon at any subsequent meeting, unless the proxy expressly provides for this.

Special/Extraordinary General Meetings

Delaware

Under Delaware law, special meetings of stockholders may be called by the board of directors or by such other person or persons authorized to do so by the corporation's certificate of incorporation or bylaws. At a special meeting, only the business set forth in the notice of meeting may be conducted.

Ireland

Extraordinary general meetings may be convened (1) by our board of directors, (2) on requisition of our shareholders holding not less than 10% of the paid up share capital of our carrying voting rights, (3) on requisition of our auditors, or (4) in exceptional cases, by order of a court. Extraordinary general meetings are generally held for the purpose of approving shareholder resolutions of our company as may be required from time to time. At any extraordinary general meeting only such business shall be conducted as is set forth in the notice thereof.

In the case of an extraordinary general meeting convened by our shareholders, the proposed purpose of the meeting must be set out in the requisition notice. Upon receipt of any such valid requisition notice, our board of directors has 21 days to convene a meeting of our shareholders to vote on the matters set out in the requisition notice. This meeting must be held within two months of the receipt of the requisition notice. If our board of directors does not convene the meeting within such 21-day period, the requisitioning shareholders, or any of them representing more than one half of the total voting rights of all of them, may themselves convene a meeting, which meeting must be held within three months of the receipt of the requisition notice.

Under Irish law, if our board of directors becomes aware that our net assets are not greater than half of the amount of our called-up share capital, it must convene an extraordinary general meeting of our shareholders not later than 28 days from the date that our directors learn of this fact to consider how to address the situation.

Record Date; Notice Provisions for Meetings of Shareholders

Delaware

Under Delaware law, unless otherwise provided in the certificate of incorporation or bylaws or under other portions of Delaware law, written notice of any meeting of the stockholders must be given to each stockholder entitled to vote at the meeting not less than 10 nor more than 60 days before the date of the meeting and must specify the place, if any, date, hour, means of remote communications, if any, by which stockholders and proxy holders may be deemed to be present in person and vote at such meeting, the record date for determining the stockholders entitled to vote at the meeting, if such date is different from the record date for determining stockholders entitled to notice of the meeting, and, in the case of a special meeting, the purpose or purposes of the meeting.

Shareholder Quorum Voting Rights

Delaware law provides that, unless otherwise provided in the certificate of incorporation, each stockholder is entitled to one vote for each share of capital stock held by such stockholder.

Ireland

Our Articles provide that our directors may, from time to time, fix a record date for the purposes of determining the rights of members to notice of and/or to vote at any general meeting, but that such record date shall be not more than 80 nor less than 10 days before the date of such meeting. Our Articles provide that if no record date is fixed by our directors, the record date for determining members entitled to notice of or to vote at a meeting of the members shall be the close of business on the day next preceding the day on which notice is given.

Notice of an annual general meeting must be given to all of our shareholders and to our auditors. Our Articles provide that the maximum notice period is 60 days. The minimum notice period is 21 days' notice in writing for an annual general meeting.

Under our Articles, each holder of our ordinary shares is entitled to one vote for each of ordinary share that he or she holds as of the record date for the meeting. The holders of our deferred ordinary shares are not entitled to a vote. We may not exercise any voting rights in respect of any shares held as treasury shares. Any shares held by our subsidiaries will count as treasury shares for this purpose, and such subsidiaries cannot therefore exercise any voting rights in respect of those shares. Irish law distinguishes between "ordinary business" and "special business." Most business that is transacted at a general meeting is deemed "special" with the exception of declaring a dividend, the consideration of the statutory financial statements and the reports of the directors and auditors thereon, the review by the shareholders of the company's affairs, the fixing of the remuneration of auditors and the election of directors, all of which are deemed to be "ordinary business."

Delaware

Ireland

Our Articles provide that, except where a greater majority is required by the Irish Companies Act (such as any matters that require special resolutions of the shareholders) as described below, any question, business or resolution proposed at any general meeting shall be decided by a simple majority of the votes cast. All resolutions proposed at our general meetings will be decided on a poll. Every shareholder entitled to vote has one vote for each share held unless otherwise provided in our Articles. Voting rights may be exercised by shareholders registered in the share register as of the record date for the meeting or by a duly appointed proxy of such a registered shareholder, which proxy need not be a shareholder. Where interests in shares are held by a nominee trust company, this company may exercise the rights of the beneficial holders on their behalf as their proxy. All proxies must be appointed in accordance with our Articles. Our Articles permit the appointment of proxies by our shareholders to be notified to us electronically, when permitted by our directors. Abstentions, including persons indicating a vote to be withheld, blank votes and broker non-votes will not be counted for the purposes of establishing the number of votes cast for the purposes of determining whether an ordinary resolution (requiring a simple majority of votes cast) or a special resolution (requiring the support of 75%) has been approved.

Treasury shares will not be entitled to vote at general meetings of shareholders.

Our Articles provide that shareholder resolutions are to be adopted by way of poll at meetings and shareholders are not permitted to pass resolutions by unanimous written consent.

Action by Written Consent

Under Delaware law, unless otherwise provided in the certificate of incorporation or bylaws, any action required or permitted to be taken at a meeting of stockholders may be taken without a meeting if a written consent to the action is signed by stockholders holding at least a majority of the voting power. If a different proportion of voting power is required for an action at a meeting, then that proportion of written consents is also required.

Derivative or Other Suits

Delaware

Under Delaware law, a stockholder may bring a derivative action on behalf of the corporation to enforce the rights of the corporation. Generally, a person may institute and maintain such a suit only if such person was a stockholder at the time of the transaction that is the subject of the suit or his or her shares thereafter devolved upon him or her by operation of law. Delaware law also requires that the derivative plaintiff make a demand on the directors of the corporation to assert the corporate claim before the suit may be prosecuted by the derivative plaintiff, unless such demand would be futile.

An individual also may commence a class action suit on behalf of himself or herself and other similarly situated stockholders where the requirements for maintaining a class action have been met.

Ireland

In certain limited circumstances, a shareholder may be entitled to bring a derivative action on our behalf if a wrong committed against us would otherwise go unredressed.

The principal case law in Ireland indicates that to bring a derivative action a person must first establish a prima facie case (1) that a company is entitled to the relief claimed and (2) that the action falls within one of the five exceptions derived from case law, as follows:

- where an ultra vires or illegal act is perpetrated;
- where more than a bare majority is required to ratify the “wrong” complained of;
- where the shareholders’ personal rights are infringed;
- where a fraud has been perpetrated upon a minority by those in control; and
- where the justice of the case requires a minority to be permitted to institute proceedings.

Irish law also permits shareholders of a company to bring proceedings against that company where its affairs are being conducted, or the powers of the directors are being exercised, in a manner oppressive to the shareholders or in disregard of their interests. The court can grant any relief it sees fit and the usual remedy is the purchase or transfer of the shares of any shareholder.

Business Combinations with Interested Shareholders

Delaware

Under Delaware law, with limited exceptions, a merger, consolidation or sale of all or substantially all of the assets of a Delaware corporation must be approved by the board of directors and a majority of the issued and outstanding shares entitled to vote thereon. However, Section 203 of the DGCL generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with an interested stockholder for a period of three years following the date on which the stockholder became an interested stockholder, unless, among other exceptions, such transactions are approved by the board of directors before such interested stockholder became such.

Ireland

Irish law does not generally require shareholder approval for a sale, lease or exchange of all or substantially all of a company's property and assets, however, our Articles provide that the affirmative vote of the holders of a majority of our outstanding voting shares on the relevant record date is required to approve a sale, lease or exchange of all or substantially all of our property or assets.

Our Articles also include a provision similar to Section 203 of the DGCL, which generally prohibits us from engaging in a business combination with an interested shareholder for a period of three years following the date the person became an interested shareholder, unless, in general:

- our board of directors approved the transaction which resulted in the shareholder becoming an interested shareholder;
- upon consummation of the transaction which resulted in the shareholder becoming an interested shareholder, the shareholder owned at least 85% of the voting shares outstanding at the time of commencement of such transaction, excluding for purposes of determining the number of voting shares outstanding (but not the outstanding voting shares owned by the interested shareholder), voting shares owned by persons who are directors and also officers and by certain employee share plans; or
- the business combination is approved by our board of directors and authorized at an annual or extraordinary general meeting of shareholders by the affirmative vote of the holders of at least 75% of the outstanding voting shares that are not owned by the interested shareholder.

A "business combination" is generally defined as a merger, asset or stock sale or other transaction resulting in a financial benefit to the interested shareholder. An "interested shareholder" is generally defined as a person who, together with affiliates and associates, owns or, within three years prior to the date in question, owned 15% or more of our outstanding voting shares.

Appraisal Rights

Delaware

Under Delaware law, holders of shares of any class or series of stock of a constituent corporation in a merger or consolidation have the right, in certain circumstances, to dissent from such merger or consolidation by demanding payment in cash for their shares equal to the fair value of such shares, exclusive of any element of value arising from the accomplishment or expectation of the merger or consolidation, as determined by a court in an action timely brought by the corporation or the dissenters. Delaware law grants dissenters appraisal rights only in the case of mergers or consolidations and not in the case of a sale or transfer of assets or a purchase of assets for stock, regardless of the number of shares being issued. No appraisal rights are available for shares of any class or series of stock that are listed on a national securities exchange or held of record by more than 2,000 holders, unless the agreement of merger or consolidation requires the holders thereof to accept for such shares anything other than: shares of stock of the surviving corporation; shares of stock of another corporation, which shares of stock are either listed on a national securities exchange or held of record by more than 2,000 holders; cash in lieu of fractional shares of the stock described in the first two points above; or some combination of the above.

In addition, appraisal rights are not available for stockholders of a surviving corporation in a merger if the merger did not require the vote of the stockholders of the surviving corporation.

Amendments of Constituent Documents

Under Delaware law, a corporation may amend its certificate of incorporation, from time to time, in any and as many respects as may be desired, so long as its certificate of incorporation as amended would contain only such provisions as it would be lawful and proper to insert in an original certificate of incorporation filed at the time of the filing of the amendment; and, if a change in stock or the rights of stockholders, or an exchange, reclassification, subdivision, combination or cancellation of stock or rights of stockholders is to be made, such provisions as may be necessary to effect such change, exchange, reclassification, subdivision, combination or cancellation.

Ireland

Generally, under Irish law, shareholders of an Irish company do not have dissenters' or appraisal rights. Under the European Communities (Cross-Border Mergers) Regulations 2008, as amended, governing the merger of an Irish company limited by shares such as the company and a company incorporated in the EEA, a shareholder (1) who voted against the special resolution approving the merger or (2) of a company in which 90% of the shares are held by the other party to the merger, has the right in certain circumstances to request that the successor company acquire his or her shares for cash at a price determined in accordance with the share exchange ratio set out in the merger agreement.

Irish companies may only alter their memorandum and articles of association by a resolution of shareholders approved by 75% of the votes cast at a general meeting. An Irish company is not permitted to opt out of this requirement.

Delaware

The board of directors must adopt a resolution setting forth the amendment proposed, declaring its advisability and either calling a special meeting of the stockholders entitled to vote in respect thereof for the consideration of such amendment or directing that the amendment proposed be considered at the next annual meeting of the stockholders. A majority of the outstanding shares entitled to vote thereon and a majority of the outstanding shares of each class entitled to vote thereon as a class must vote in favor of the amendment.

The holders of the outstanding shares of a class must be entitled to vote as a class upon a proposed amendment, whether or not entitled to vote thereon by the certificate of incorporation, if the amendment would increase or decrease the aggregate number of authorized shares of such class, increase or decrease the par value of the shares of such class, or alter or change the powers, preferences, or special rights of the shares of such class so as to affect them adversely.

Upon the dissolution of a Delaware corporation, after satisfaction of the claims of creditors, the assets of that corporation would be distributed to stockholders in accordance with their respective interests, including any rights a holder of shares of preference shares may have to preferred distributions upon dissolution or liquidation of the corporation.

Ireland

The rights of our shareholders to a return of our assets on dissolution or winding up, following the settlement of all claims of creditors, may be prescribed in our Articles or the terms of any preferred shares we issue from time to time. The holders of our preferred shares in particular may have the right to priority in the event of our dissolution or winding up. If our Articles contain no specific provisions in respect of dissolution or winding up, then, subject to the priorities of any creditors, the assets will be distributed to our shareholders in proportion to the paid-up nominal value of the shares held. Our Articles provide that our ordinary shareholders are entitled to participate pro rata in a winding up, but their right to do so may be subject to the rights of any preferred shareholders to participate under the terms of any series or class of preferred shares.

Dissolution and Winding Up

Delaware

Ireland

Enforcement of Judgment Rendered by U.S. Court

A judgment for the payment of money rendered by a court in the United States based on civil liability generally would be enforceable elsewhere in the United States.

We may be dissolved and wound up at any time by way of a shareholders' voluntary winding up or a creditors' winding up. In the case of a shareholders' voluntary winding up, a special resolution of shareholders is required. We may also be dissolved by way of court order on the application of a creditor, or by the Companies Registration Office as an enforcement measure where we have failed to file certain returns. We may also be dissolved by the Director of Corporate Enforcement in Ireland where our affairs have been investigated by an inspector and it appears from the report or any information obtained by the Director of Corporate Enforcement that we should be wound up.

A judgment for the payment of money rendered by a court in the United States based on civil liability would not be automatically enforceable in Ireland. There is no treaty between Ireland and the United States providing for the reciprocal enforcement of foreign judgments. The following requirements must be met before the U.S. judgment will be deemed to be enforceable in Ireland:

- the U.S. judgment must be for a definite sum;
- the U.S. judgment is not directly or indirectly for the payment of taxes or other charges of a like nature or a fine or other penalty, for example, punitive or exemplary damages;
- the U.S. judgment must be final and conclusive;
- the Irish proceedings were commenced within the relevant limitation period;
- the U.S. judgment must be provided by a court of competent jurisdiction, as determined by Irish law; and
- the U.S. judgment remains valid and enforceable in the U.S. court in which it was obtained.

An Irish court will also exercise its right to refuse judgment if the U.S. judgment was obtained by fraud, violated Irish public policy, is in breach of natural justice or is irreconcilable with an earlier foreign judgment.

Anti-Takeover Provisions

Business Combinations with Interested Shareholders

Our Articles include a provision similar to Section 203 of the Delaware General Corporation Law, which generally prohibits us from engaging in a business combination with an interested shareholder for a period of three years following the date the person became an interested shareholder, unless, in general:

- our board of directors approved the transaction which resulted in the shareholder becoming an interested shareholder;
- upon consummation of the transaction which resulted in the shareholder becoming an interested shareholder, the shareholder owned at least 85% of the voting shares outstanding at the time of commencement of such transaction, excluding for purposes of determining the number of voting shares outstanding (but not the outstanding voting shares owned by the interested shareholder), voting shares owned by persons who are directors and also officers and by certain employee share plans; or
- the business combination is approved by our board of directors and authorized at an annual or extraordinary general meeting of shareholders by the affirmative vote of the holders of at least 75% of the outstanding voting shares that are not owned by the interested shareholder.

A “business combination” is generally defined as a merger, asset or stock sale or other transaction resulting in a financial benefit to the interested shareholder. An “interested shareholder” is generally defined as a person who, together with affiliates and associates, owns or, within three years prior to the date in question, owned 15% or more of our outstanding voting shares.

Irish Takeover Rules and Substantial Acquisition Rules

A transaction in which a third party seeks to acquire 30% or more of our voting rights and any other acquisitions of our securities will be governed by the Irish Takeover Panel Act 1997 and the Irish Takeover Rules made thereunder, or the Irish Takeover Rules, and will be regulated by the Irish Takeover Panel. The “General Principles” of the Irish Takeover Rules and certain important aspects of the Irish Takeover Rules are described below.

General Principles

The Irish Takeover Rules are built on the following General Principles which will apply to any transaction regulated by the Irish Takeover Panel:

- in the event of an offer, all holders of securities of the target company must be afforded equivalent treatment and, if a person acquires control of a company, the other holders of securities must be protected;
- the holders of securities in the target company must have sufficient time and information to enable them to reach a properly informed decision on the offer; where it advises the holders of securities, the board of directors of the target company must give its views on the effects of the implementation of the offer on employment, employment conditions and the locations of the target company’s place of business;
- a target company’s board of directors must act in the interests of that company as a whole and must not deny the holders of securities the opportunity to decide on the merits of the offer;
- false markets must not be created in the securities of the target company, the bidder or any other company concerned by the offer in such a way that the rise or fall of the prices of the securities becomes artificial and the normal functioning of the markets is distorted;

- a bidder can only announce an offer after ensuring that he or she can fulfill in full the consideration offered, if such is offered, and after taking all reasonable measures to secure the implementation of any other type of consideration;
- a target company may not be hindered in the conduct of its affairs longer than is reasonable by an offer for its securities; and
- a “substantial acquisition” of securities, whether such acquisition is to be effected by one transaction or a series of transactions, shall take place only at an acceptable speed and shall be subject to adequate and timely disclosure.

Mandatory Bid

Under certain circumstances, a person who acquires shares, or other voting securities, of a company may be required under the Irish Takeover Rules to make a mandatory cash offer for the remaining outstanding voting securities in that company at a price not less than the highest price paid for the securities by the acquiror, or any parties acting in concert with the acquiror, during the previous 12 months. This mandatory bid requirement is triggered if an acquisition of securities would increase the aggregate holding of an acquiror, including the holdings of any parties acting in concert with the acquiror, to securities representing 30% or more of the voting rights in a company, unless the Irish Takeover Panel otherwise consents. An acquisition of securities by a person holding, together with its concert parties, securities representing between 30% and 50% of the voting rights in a company would also trigger the mandatory bid requirement if, after giving effect to the acquisition, the percentage of the voting rights held by that person, together with its concert parties, would increase by 0.05% within a 12-month period. Any person, excluding any parties acting in concert with the holder, holding securities representing more than 50% of the voting rights of a company is not subject to these mandatory offer requirements in purchasing additional securities.

Voluntary Bid; Requirements to Make a Cash Offer and Minimum Price Requirements

If a person makes a voluntary offer to acquire our outstanding ordinary shares, the offer price must not be less than the highest price paid for our ordinary shares by the bidder or its concert parties during the three-month period prior to the commencement of the offer period. The Irish Takeover Panel has the power to extend the “look back” period to 12 months if the Irish Takeover Panel, taking into account the General Principles, believes it is appropriate to do so.

If the bidder or any of its concert parties has acquired our ordinary shares (1) during the 12-month period prior to the commencement of the offer period that represent more than 10% of our total ordinary shares or (2) at any time after the commencement of the offer period, the offer must be in cash or accompanied by a full cash alternative and the price per ordinary share must not be less than the highest price paid by the bidder or its concert parties during, in the case of clause (1), the 12-month period prior to the commencement of the offer period or, in the case of (2), the offer period. The Irish Takeover Panel may apply this Rule to a bidder who, together with its concert parties, has acquired less than 10% of our total ordinary shares in the 12-month period prior to the commencement of the offer period if the Irish Takeover Panel, taking into account the General Principles, considers it just and proper to do so.

An offer period will generally commence from the date of the first announcement of the offer or proposed offer.

Substantial Acquisition Rules

The Irish Takeover Rules also contain rules governing substantial acquisitions of shares and other voting securities which restrict the speed at which a person may increase his or her holding of shares and rights over shares to an aggregate of between 15% and 30% of the voting rights of the company. Except in certain circumstances, an acquisition or series of acquisitions of shares or rights

over shares representing 10% or more of the voting rights of the company is prohibited, if such acquisition(s), when aggregated with shares or rights already held, would result in the acquirer holding 15% or more but less than 30% of the voting rights of the company and such acquisitions are made within a period of seven days. These rules also require accelerated disclosure of acquisitions of shares or rights over shares relating to such holdings.

Frustrating Action

Under the Irish Takeover Rules, our board of directors is not permitted to take any action that might frustrate an offer for our shares once our board of directors has received an approach that may lead to an offer or has reason to believe that such an offer is or may be imminent, subject to certain exceptions. Potentially frustrating actions such as 1) the issue of shares, options, restricted share units or convertible securities, (2) material acquisitions or disposals, (3) entering into contracts other than in the ordinary course of business or (4) any action, other than seeking alternative offers, which may result in frustration of an offer, are prohibited during the course of an offer or at any earlier time during which our board of directors has reason to believe an offer is or may be imminent. Exceptions to this prohibition are available where:

- the action is approved by our shareholders at a general meeting; or
- the Irish Takeover Panel has given its consent, where:
 - it is satisfied the action would not constitute frustrating action;
 - our shareholders holding more than 50% of the voting rights state in writing that they approve the proposed action and would vote in favor of it at a general meeting;
 - the action is taken in accordance with a contract entered into prior to the announcement of the offer, or any earlier time at which our board of directors considered the offer to be imminent; or
 - the decision to take such action was made before the announcement of the offer and either has been at least partially implemented or is in the ordinary course of business.

Shareholders' Rights Plan

Irish law does not expressly authorize or prohibit companies from issuing share purchase rights or adopting a shareholder rights plan as an anti-takeover measure. However, there is no directly relevant case law on the validity of such plans under Irish law. In addition, such a plan would be subject to the Irish Takeover Rules and the General Principles underlying the Irish Takeover Rules. Our Articles allow our board of directors to adopt a shareholder rights plan upon such terms and conditions as our board of directors deems expedient and in the best interests of us, subject to applicable law.

Subject to the Irish Takeover Rules, our board of directors also has power to issue any of our authorized and unissued shares on such terms and conditions as it may determine and any such action should be taken in our best interests. It is possible, however, that the terms and conditions of any issue of preference shares could discourage a takeover or other transaction that holders of some or a majority of the ordinary shares believe to be in their best interests or in which holders might receive a premium for their shares over the then-market price of the shares.

Disclosure of Interests in Shares

Under the Irish Companies Act, our shareholders must notify us if, as a result of a transaction, the shareholder will become interested in three percent or more of our voting shares, or if as a result of a transaction a shareholder who was interested in three percent or more of our voting shares ceases to be so interested. Where a shareholder is interested in three percent or more of our voting shares, the shareholder must notify us of any alteration of his or her interest that brings his or her total

holding through the nearest whole percentage number, whether an increase or a reduction. The relevant percentage figure is calculated by reference to the aggregate nominal value of the voting shares in which the shareholder is interested as a proportion of the entire nominal value of our issued share capital (or any such class of share capital in issue). Where the percentage level of the shareholder's interest does not amount to a whole percentage, this figure may be rounded down to the next whole number. We must be notified within five business days of the transaction or alteration of the shareholder's interests that gave rise to the notification requirement. If a shareholder fails to comply with these notification requirements, the shareholder's rights in respect of any of our shares it holds will not be enforceable, either directly or indirectly. However, such person may apply to the court to have the rights attaching to such shares reinstated.

In addition to these disclosure requirements, we, under the Irish Companies Act, may, by notice in writing, require a person whom we know or have reasonable cause to believe to be, or at any time during the three years immediately preceding the date on which such notice is issued to have been, interested in shares comprised in our relevant share capital to (i) indicate whether or not it is the case and (ii) where such person holds or has during that time held an interest in our shares, to provide additional information, including the person's own past or present interests in our shares. If the recipient of the notice fails to respond within the reasonable time period specified in the notice, we may apply to the Irish court for an order directing that the affected shares be subject to certain restrictions, as prescribed by the Irish Companies Act, as follows:

- any transfer of those shares or, in the case of unissued shares, any transfer of the right to be issued with shares and any issue of shares, shall be void;
- no voting rights shall be exercisable in respect of those shares;
- no further shares shall be issued in right of those shares or in pursuance of any offer made to the holder of those shares; and
- no payment shall be made of any sums due from us on those shares, whether in respect of capital or otherwise.

The court may also order that shares subject to any of these restrictions be sold with the restrictions terminating upon the completion of the sale.

In the event we are in an offer period pursuant to the Irish Takeover Rules, accelerated disclosure provisions apply for persons holding an interest in our securities of one percent or more.

Certain other provisions of Irish law or our Articles may be considered to have anti-takeover effects, including those described under the following captions: “—Authorized Share Capital” (regarding issuance of preference shares), “—Preemption Rights, Share Warrants and Share Options,” “—Corporate Governance,” “—Differences in Corporate Law Between Ireland and The State Of Delaware—Election of Directors,” “—Differences in Corporate Law Between Ireland and The State Of Delaware—Removal of Directors,” “—Differences in Corporate Law Between Ireland and The State of Delaware—Business Combinations with Interested Shareholders,” “—Differences in Corporate Law Between Ireland and The State Of Delaware—Amendments of Constituent Documents,” “—Differences in Corporate Law Between Ireland and The State Of Delaware—Advance Notice Provisions,” and “—Differences in Corporate Law Between Ireland and The State Of Delaware—Special/Extraordinary General Meetings.”

Registration Rights

In February 2015, we entered into an Investors' Rights Agreement with certain holders of our ordinary shares that grants to the holders certain demand, Form F-3 and piggyback registration rights for their ordinary shares. We refer to the ordinary shares with these registration rights as “registrable securities.” These holders have agreed not to exercise any registration rights they may acquire until the date beginning 180 days after the date of this prospectus.

The following is a summary of the registration rights.

Demand Registration Rights

Holders of registrable securities representing at least 25% of our registrable securities may request that we file with the SEC a registration statement on Form F-1 for an aggregate offering price to the public of not less than \$5 million with respect to our registrable securities then outstanding. However, we will not be required to effect a registration on Form F-1 (i) during the period that is 90 days before our good faith estimate of the date of filing of, and ending on a date that is 180 days after the effective date of a registration we have initiated, (ii) during any 12 month period after we have effected two demand registrations during such 12 month period, (iii) if we deliver notice to the holders of registrable securities within 30 days of any such demand registration request of our intent to file a registration statement for an IPO within 60 days, (iv) if the holders propose to dispose of registrable securities that may be immediately registered on Form F-3, or (v) if we have effected two registrations pursuant to Form F-3 registration demands within the 12 month period immediately preceding the date of such request. In an underwritten offering, the managing underwriter, if any, has the right, subject to specified conditions, to limit the number of ordinary shares such holders may include. If at any time we are not qualified to use a Form F-1, these demand registration rights apply to a demand registration on Form S-1.

Form F-3 Registration Rights

Holders of registrable securities can make a written request that we register their shares on Form F-3, if we are eligible to file a registration statement on Form F-3, and having an anticipated aggregate offering price, net of selling expenses, of at least \$2 million. However, we are not obligated to effect more than two Form F-3 registrations during any 12 month period. We may defer a Form F-3 filing for up to 90 days once during any 12 month period. If at any time we are not qualified to use a Form F-3, these demand registration rights shall apply to a demand registration on Form S-3.

Piggyback Registration Rights

If we propose to register our ordinary shares under the Securities Act in connection with a public offering of such securities solely for cash, we must promptly give each holder notice of such registration. Holders may request that their registrable securities be included in such registration.

Expenses of Registration

We will pay the registration expenses of the holders of ordinary shares registered pursuant to the demand, Form F-3, and piggyback registration rights described above. We will also pay the fees, not to exceed \$35,000, of one counsel to the selling holders.

Expiration of Registration Rights

The demand, Form F-3 and piggyback registration rights described above will expire as to any holder of registrable securities when Rule 144 or another similar exemption under the Securities Act is available for the sale of all of such holder's shares without limitation during a three-month period without registration. The registration rights will also terminate upon specified corporate events, including the closing of a merger, consolidation or share exchange of us with or into another entity.

Listing

Our ordinary shares have been approved for listing on The NASDAQ Global Select Market under the symbol "SBBP."

Transfer Agent and Registrar

Upon the completion of this offering, the transfer agent and registrar for our ordinary shares will be Computershare, Inc. The transfer agent and registrar's address is 250 Royall Street, Canton, MA 02021.

ORDINARY SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been no market for our ordinary shares. Future sales of substantial amounts of our ordinary shares in the public market could adversely affect market prices prevailing from time to time. Furthermore, because only a limited number of ordinary shares will be available for sale shortly after this offering due to existing contractual and legal restrictions on resale as described below, there may be sales of substantial amounts of our ordinary shares in the public market after such restrictions lapse. This may adversely affect the prevailing market price and our ability to raise equity capital in the future.

Upon completion of this offering, we will have 21,205,382 ordinary shares outstanding, assuming no exercise of the underwriters' option to purchase additional ordinary shares. Of these shares, 7,792,838 ordinary shares, or 8,167,838 ordinary shares if the underwriters exercise their option to purchase 375,000 additional ordinary shares in full, will be freely transferable without restriction or registration under the Securities Act, except for any ordinary shares purchased by one of our existing "affiliates," as that term is defined in Rule 144 under the Securities Act. The remaining ordinary shares existing are "restricted shares" as defined in Rule 144. Restricted shares may be sold in the public market only if registered or if they qualify for an exemption from registration under Rules 144 or 701 of the Securities Act. As a result of the contractual lock-up period described below and the provisions of Rules 144 and 701, these shares will be available for sale in the public market as follows:

Rule 144

In general, a person who has beneficially owned our ordinary shares that are restricted shares for at least six months would be entitled to sell such securities, provided that (1) such person is not deemed to have been one of our affiliates at the time of, or at any time during the 90 days preceding, a sale and (2) we are subject to the Exchange Act periodic reporting requirements for at least 90 days before the sale. Persons who have beneficially owned our ordinary shares that are restricted shares for at least six months but who are our affiliates at the time of, or any time during the 90 days preceding, a sale, would be subject to additional restrictions, by which such person would be entitled to sell within any three month period only a number of securities that does not exceed the greater of either of the following:

- 1% of the number of our ordinary shares then outstanding, which will equal approximately 212,000 ordinary shares immediately after this offering, assuming no exercise of the underwriters' option to purchase additional shares; or
- the average weekly trading volume of our ordinary shares on the during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale; provided, in each case, that we are subject to the Exchange Act periodic reporting requirements for at least 90 days before the sale. Such sales both by affiliates and by non-affiliates must also comply with the manner of sale, current public information and notice provisions of Rule 144 to the extent applicable.

Rule 701

In general, under Rule 701, any of our employees, directors, officers, consultants or advisors who purchases shares from us in connection with a compensatory share or option plan or other written agreement before the effective date of this offering is entitled to resell such shares 90 days after the effective date of this offering in reliance on Rule 144, without having to comply with the holding period requirements or other restrictions contained in Rule 701.

The SEC has indicated that Rule 701 will apply to typical share options granted by an issuer before it becomes subject to the reporting requirements of the Exchange Act, along with the shares

acquired upon exercise of such options, including exercises after the date of this prospectus. Securities issued in reliance on Rule 701 are restricted securities and, subject to the contractual restrictions described below, beginning 90 days after the date of this prospectus, may be sold by persons other than “affiliates,” as defined in Rule 144, subject only to the manner of sale provisions of Rule 144 and by “affiliates” under Rule 144 without compliance with its one-year minimum holding period requirement.

Regulation S

Regulation S provides generally that sales made in offshore transactions are not subject to the registration or prospectus-delivery requirements of the Securities Act.

Lock-up Agreements

All of our directors and executive officers and certain holders of our capital stock have agreed, subject to limited exceptions, not to offer, pledge, announce the intention to sell, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase or otherwise dispose of, directly or indirectly, or enter into any swap or other agreement that transfers, in whole or in part, any of the economic consequences of ownership of the ordinary shares or such other securities for a period of up to 180 days after the date of this prospectus, subject to certain exceptions, without the prior written consent of Stifel, Nicolaus & Company, Incorporated. See “Underwriting.”

Equity Plans

We intend to file one or more registration statements on Form S-8 under the Securities Act to register ordinary subject to outstanding stock options and ordinary shares issued or issuable under our stock plans. We expect to file the registration statement covering shares offered pursuant to our stock plans on or shortly after the date of this prospectus, permitting the resale of such shares by nonaffiliates in the public market without restriction under the Securities Act and the sale by affiliates in the public market, subject to compliance with the resale provisions of Rule 144.

TAXATION

The following summary contains a description of the material Irish and U.S. federal income tax consequences of the acquisition, ownership and disposition of ordinary shares, but it does not purport to be a comprehensive description of all the tax considerations that may be relevant to a decision to purchase ordinary shares. The summary is based upon the tax laws of Ireland and regulations thereunder and on the tax laws of the United States and regulations thereunder as of the date hereof, which are subject to change.

Irish Tax Considerations

Scope of Discussion

The following is a summary of the material Irish tax considerations applicable to certain investors who are the beneficial owners of our ordinary shares. This summary is based on existing Irish tax law and our understanding of the practices of the Irish Revenue Commissioners as of the date of this prospectus. Legislative, administrative or judicial changes may modify the tax consequences described in this summary, possibly with retroactive effect. Furthermore, we can provide no assurances that the tax consequences contained in this summary will not be challenged by the Irish Revenue Commissioners or will be sustained by an Irish court if they were to be challenged.

This summary does not constitute tax advice and is intended only as a general guide. This summary is not exhaustive and shareholders should consult their own tax advisers about the Irish tax consequences (and the tax consequences under the laws of other relevant jurisdictions), which may arise as a result of being a shareholder in our company including the acquisition, ownership and disposition of our ordinary shares. Furthermore, this summary applies only to shareholders who will hold our ordinary shares as capital assets and does not apply to all categories of shareholders, such as dealers in securities, trustees, insurance companies, collective investment schemes, pension funds or shareholders who have, or who are deemed to have, acquired their shares by virtue of an office or employment performed or carried on in Ireland.

Irish Tax on Chargeable Gains

Non-Resident Shareholders

Shareholders who are not resident or ordinarily resident in Ireland for Irish tax purposes should not be liable to Irish tax on chargeable gains realized on a disposal of our ordinary shares unless such shares are used, held or acquired for the purpose of a trade or business carried on by such a shareholder in Ireland through a branch or an agency.

A shareholder who is an individual and who is temporarily a non-resident in Ireland may, under Irish anti-avoidance legislation, still be liable to Irish tax on any chargeable gain realized on a disposal of our ordinary shares during the period in which the individual is non-resident.

Irish Dividend Withholding Tax

Our company does not anticipate paying dividends for the foreseeable future. However, if in the future we were to pay a dividend or make a distribution to our shareholders, that distribution may be subject to dividend withholding tax, or DWT, at the standard rate of Irish income tax (currently 20%) unless one of the exemptions described below applies.

For DWT purposes, a dividend includes any distribution made to shareholders, including cash dividends, non-cash dividends and any additional shares taken in lieu of a cash dividend. We are responsible for withholding DWT at source in respect of the distributions made and remitting the tax withheld to the Irish Revenue Commissioners.

General Exemptions

Certain shareholders, both individual and corporate, are entitled to an exemption from DWT. In particular, dividends paid to a non-Irish resident shareholder will not be subject to DWT where the shareholder is beneficially entitled to the dividend and is:

- an individual shareholder resident for tax purposes in a “relevant territory” and the individual is neither resident nor ordinarily resident in Ireland;
- a corporate shareholder that is resident for tax purposes in a “relevant territory,” but is not under the control, whether directly or indirectly, of a person or persons who is or are resident in Ireland;
- a corporate shareholder that is not resident for tax purposes in Ireland and that is ultimately controlled, directly or indirectly, by persons resident in a “relevant territory;”
- a corporate shareholder that is not resident for tax purposes in Ireland and whose principal class of shares, or those of its 75% parent, is substantially and regularly traded on a recognized share exchange in a “relevant territory” or on such other share exchange as may be approved by the Irish Minister for Finance; or
- a corporate shareholder that is not resident for tax purposes in Ireland and is wholly-owned, directly or indirectly, by two or more companies where the principal class of shares of each of such companies is substantially and regularly traded on a recognized share exchange in a “relevant territory” or on such other share exchange as may be approved by the Irish Minister for Finance;

and provided, in all cases noted above (but subject to “Shares Held by U.S. Resident Shareholders” below), Strongbridge Biopharma plc or, in respect of Strongbridge Biopharma plc shares held through DTC, any qualifying intermediary appointed by Strongbridge Biopharma plc, has received from the shareholder, where required, the relevant DWT Forms prior to the payment of the dividend. In practice, in order to ensure sufficient time to process the receipt of relevant DWT Forms, the Strongbridge Biopharma plc shareholder where required should furnish the relevant DWT Form to:

- its broker (and the relevant information is further transmitted to any qualifying intermediary appointed by Strongbridge Biopharma plc) before the record date for the dividend (or such later date before the dividend payment date as may be notified to the shareholder by the broker) if its shares are held through DTC; or
- Strongbridge Biopharma plc’s transfer agent at least seven business days before the record date for the dividend if its shares are held outside of DTC.

A list of “relevant territories” for the purposes of DWT, as of the date of this prospectus, is set forth below and this list is subject to change:

Albania	Czech Republic	Italy	Netherlands	Slovenia
Armenia	Denmark	Japan	New Zealand	South Africa
Australia	Egypt	Republic of Korea	Norway	Spain
Austria	Estonia	Kuwait	Pakistan	Sweden
Bahrain	Ethiopia	Latvia	Panama	Switzerland
Belarus	Finland	Lithuania	Poland	Thailand
Belgium	France	Luxembourg	Portugal	Turkey
Bosnia and Herzegovina	Georgia	Macedonia	Qatar	Ukraine
Botswana	Germany	Malaysia	Romania	United Arab Emirates
Bulgaria	Greece	Malta	Russia	United Kingdom
Canada	Hong Kong	Mexico	Saudi Arabia	United States of America
Chile	Hungary	Moldova	Serbia	Uzbekistan
China	Iceland	Montenegro	Singapore	Vietnam
Croatia	India	Morocco	Slovak Republic	Zambia
Cyprus	Israel			

It is the responsibility of each individual shareholder to determine whether or not they are a “resident” for tax purposes in a “relevant territory.”

Prior to paying any future dividend, our company will enter into an agreement with an institution which is recognized by the Irish Revenue Commissioners as a “qualifying intermediary” and which satisfies the requirements for dividends to be paid to certain shareholders free from DWT where such shareholders hold their shares through DTC, as described below. The agreement will generally provide for certain arrangements relating to distributions in respect of those shares that are held through DTC. The agreement will provide that the “qualifying intermediary” shall distribute or otherwise make available to Cede & Co., as nominee for DTC, any cash dividend or other cash distribution to be made to holders of the deposited securities, after we deliver or cause to be delivered to the “qualifying intermediary” the cash to be distributed.

We will rely on the information received directly or indirectly from brokers and their transfer agent in determining where shareholders reside and whether they have furnished the required U.S. tax information, as described below. Shareholders who are required to furnish Irish DWT declaration forms in order to receive their dividends without DWT should note that those declarations forms are only valid for five years and new DWT declarations forms must be completed and filed before the expiration of that five year period to enable the shareholder continue to receive dividends without DWT.

Shares Held by U.S. Resident Shareholders

Dividends paid on our ordinary shares that are owned by residents of the United States should not be subject to DWT, subject to the completion and delivery of the relevant forms to us.

Residents of the United States who hold their shares through DTC should be entitled to receive dividends without DWT provided that the address of the beneficial owner of the shares in the records of the broker holding such shares is in the United States. We would strongly recommend that such shareholders ensure that their information has been properly recorded by their brokers so that such brokers can further transmit the relevant information to a qualifying intermediary appointed by us.

Residents of the United States who hold their shares outside of DTC will be entitled to receive dividends without DWT provided that the shareholder has completed the relevant Irish DWT

declaration form and this declaration form remains valid. Such shareholders must provide the relevant Irish DWT declaration form to our transfer agent at least seven business days before the record date of the dividend payment to which they are entitled. We would strongly recommend that such shareholders complete the relevant Irish DWT declaration form and provide them to our transfer agent as soon as possible after acquiring shares in our company.

If a U.S. resident shareholder is entitled to an exemption from DWT, but receives a dividend subject to DWT, that shareholder may be entitled to claim a refund of DWT from the Irish Revenue Commissioners, subject to certain time limits and provided the shareholder is beneficially entitled to the dividend.

Shares Held by Residents of “Relevant Territories” Other Than the United States

Shareholders who are residents of “relevant territories” other than the United States, and who are entitled to an exemption from DWT, must complete the relevant Irish DWT declaration form in order to receive dividends without DWT.

Shareholders must provide the relevant Irish DWT declaration form to their brokers so that such brokers can further transmit the relevant information to a qualifying intermediary appointed by us before the record date of the dividend to which they are entitled, in the case of shares held through DTC, or to our transfer agent at least seven business days before such record date, in the case of shares held outside of DTC. We would strongly recommend that such shareholders complete the relevant Irish DWT declaration form and provide that form to their brokers or our transfer agent as soon as possible after acquiring shares in our company.

If a shareholder who is resident in a “relevant territory” and is entitled to an exemption from DWT receives a dividend subject to DWT, that shareholder may be entitled to claim a refund of DWT from the Irish Revenue Commissioners, subject to certain time limits and provided the shareholder is beneficially entitled to the dividend.

Notwithstanding the foregoing, the General Exemptions from DWT referred to above do not apply to an individual shareholder that is resident or ordinarily resident in Ireland or to a corporate entity that is under the control, whether directly or indirectly, of a person or persons who is or who are resident in Ireland. However, other exemptions from DWT may still be available to that shareholder. In addition, it may also be possible for certain shareholders to rely on a double tax treaty to limit the applicable DWT.

Shares Held by Other Persons

A shareholder that does not fall within one of the categories specifically mentioned above may nonetheless fall within other exemptions from DWT provided that the shareholder has completed the relevant Irish DWT declaration form and this declaration form remains valid.

If any such shareholder is exempt from DWT but receives a dividend subject to DWT, that shareholder may be entitled to claim a refund of DWT from the Irish Revenue Commissioners, subject to certain time limits.

Income Tax on Dividends Paid

Irish income tax may arise for certain shareholders in respect of any dividends received from us.

Non-Irish Resident Shareholders

A shareholder that is not resident or ordinarily resident in Ireland for Irish tax purposes and who is entitled to an exemption from DWT generally has no liability to Irish income tax or other similar charges with respect to any dividends received from us. An exception to this position may apply where a shareholder holds our ordinary shares through a branch or agency in Ireland through which a trade is carried on.

A shareholder that is not resident or ordinarily resident in Ireland for Irish tax purposes and who is not entitled to an exemption from DWT generally has no additional liability to Irish income tax or other similar charges on any dividends received from us. An exception to this position may apply where a shareholder holds our ordinary shares through a branch or an agency in Ireland through which a trade is carried on. In these circumstances, the shareholder's liability to Irish tax is effectively limited to the amount of DWT withheld by us.

Capital Acquisitions Tax

Capital acquisitions tax, or CAT, consists principally of gift tax and inheritance tax. A gift or inheritance of our ordinary shares, including where such shares are held in DTC, may attract a charge to CAT irrespective of the place of residence, ordinary residence or domicile of the transferor or the transferee of the shares. This is because a charge to CAT may arise on a gift or inheritance which comprises of property situated in Ireland. Our ordinary shares are regarded as property situated in Ireland for CAT purposes because our share register must be retained in Ireland. The person who receives the gift or inheritance is primarily liable for any CAT that may arise.

CAT is levied at a rate of 33% above certain tax-free thresholds. The appropriate tax-free threshold is dependent upon (1) the relationship between the donor and the donee and (2) the aggregation of the values of previous gifts and inheritances received by the donee from persons within the same group threshold. Gifts and inheritances passing between spouses are exempt from CAT. Shareholders should consult their own tax advisers as to whether CAT is creditable or deductible in computing any domestic tax liabilities.

Irish Stamp Duty

The rate of stamp duty, where applicable, on the transfer of shares in an Irish incorporated company is 1% of the price paid or the market value of the shares acquired, whichever is greater. Where a charge to Irish stamp duty applies it is generally a liability for the transferee. Irish stamp duty may, depending on the manner in which our ordinary shares are held, be payable in respect of the transfer of our ordinary shares.

Irish Stamp Duty—DTC Arrangements

On the basis that most of our shares are expected to be held through DTC, or through brokers who hold shares on behalf of their customers through DTC, the transfer of such shares should be exempt from Irish stamp duty based on established practice of Irish Revenue Commissioners. We received written confirmation from the Irish Revenue Commissioners on June 22, 2015 that a transfer of our shares held through DTC and transferred by means of a book-entry interest would be exempt from Irish stamp duty.

Shares Held Through DTC

A transfer of our ordinary shares effected by means of the transfer of book-entry interests in DTC should not be subject to Irish stamp duty.

Shares Held Outside of DTC or Transferred Into or Out of DTC

A transfer of our ordinary shares where any of the parties to the transfer hold the shares outside of DTC may be subject to Irish stamp duty. A shareholder should be entitled to transfer our ordinary shares into, or out of, DTC without giving rise to Irish stamp duty provided (1) there is no change in beneficial ownership of the shares and (2) at the time of the transfer into, or out of, DTC, there is no agreement in place for the sale of the shares by the beneficial owner to a third party.

To avoid Irish stamp duty on transfers of our ordinary shares any directly registered shareholder may wish to consider opening a broker account, and any person who wishes to acquire our ordinary shares may wish to consider holding such shares through DTC.

DTC Requirement

In order for DTC, Cede & Co. and National Securities Clearing Corporation, or NSCC, which provides clearing services for securities that are eligible for the depository and book-entry transfer services provided by DTC and registered in the name of Cede & Co., which entities are referred to collectively as the DTC Parties, to agree to provide services with respect to our ordinary shares, we have entered into a composition agreement with the Irish Revenue Commissioners under which we have agreed to pay or procure the payment of any obligation for any Irish stamp duty or similar Irish transfer or documentary tax with respect to our ordinary shares, on (1) transfers to which any of the DTC Parties is a party or (2) which may be processed through the services of any of the DTC Parties and the DTC Parties have received confirmation from the Irish Revenue Commissioners that during the period that such composition agreement remains in force, the DTC Parties shall not be liable for any Irish stamp duty with respect to our ordinary shares.

In addition, to assure the DTC Parties that they will not be liable for any Irish stamp duty or similar Irish transfer or documentary tax with respect to our ordinary shares under any circumstances, including as a result of a change in applicable law, and to make other provisions with respect to our ordinary shares required by the DTC Parties, we and our transfer agent expect to enter into a Special Eligibility Agreement for Securities with DTC, Cede & Co. and NSCC, or the DTC Eligibility Agreement.

We expect the DTC Eligibility Agreement to provide for certain indemnities of the DTC Parties by us and Computershare, Inc. (as to which we expect to indemnify Computershare, Inc.) and to provide that DTC may impose a global lock on our ordinary shares or otherwise limit transactions in the shares, or cause the shares to be withdrawn, and NSCC may, in its sole discretion, exclude our ordinary shares from its continuous net settlement service or any other service, and any of the DTC Parties may take other restrictive measures with respect to our ordinary shares as it may deem necessary and appropriate, without any liability on the part of any of the DTC Parties, (1) at any time that it may appear to any of the DTC Parties, in any such party's sole discretion, that to continue to hold or process transactions in our ordinary shares will give rise to any Irish stamp duty or similar Irish transfer or documentary tax liability with respect to our ordinary shares on the part of any of the DTC Parties or (2) otherwise as DTC's rules or NSCC's rules provide.

Notwithstanding our entry into a composition agreement with the Irish Revenue Commissioners and the indemnities given pursuant to the DTC Eligibility Agreement, any stamp duty liability resulting from a transfer of our shares will be for the "accountable person" under Irish law (generally the transferee) and, to the extent we or a subsidiary of our company discharges such liability, on behalf of any transferee's behalf, we will seek payment or reimbursement of such liability. For further details on this point, shareholders should read the discussion under "Transfer and Registration of Shares" above.

THE IRISH TAX CONSIDERATIONS SUMMARIZED ABOVE ARE FOR GENERAL INFORMATION ONLY. EACH SHAREHOLDER SHOULD CONSULT HIS OR HER OWN TAX ADVISOR AS TO THE PARTICULAR TAX CONSEQUENCES THAT MAY APPLY TO SUCH SHAREHOLDER.

Material U.S. Federal Income Tax Considerations for U.S. Holders

The following is a description of the material U.S. federal income tax consequences to the U.S. Holders described below of owning and disposing of our ordinary shares acquired in this offering, but it does not purport to be a comprehensive description of all tax considerations that may be relevant to a particular person's decision to acquire the ordinary shares. This discussion applies only to a U.S. Holder that holds ordinary shares as capital assets for tax purposes. In addition, it does not describe all of the tax consequences that may be relevant in light of the U.S. Holder's particular circumstances, including alternative minimum tax consequences, any state or local tax considerations, any U.S. federal gift, estate or generation-skipping transfer tax consequences and tax consequences applicable to U.S. Holders subject to special rules, such as:

- certain financial institutions;
- brokers;
- dealers or traders in securities who use a mark-to-market method of tax accounting;
- real estate investment trusts;
- insurance companies;
- persons holding ordinary shares as part of a hedging transaction, straddle, wash sale, conversion transaction or integrated transaction or persons entering into a constructive sale with respect to the ordinary shares;
- regulated investment companies;
- persons whose functional currency for U.S. federal income tax purposes is not the U.S. dollar;
- entities classified as partnerships or other pass-through entities for U.S. federal income tax purposes, including persons that will hold our ordinary shares through such an entity;
- tax-exempt entities, including an "individual retirement account" or "Roth IRA;"
- persons that own or are deemed to own ten percent or more of our voting stock;
- persons that are U.S. expatriates;
- persons who acquired our ordinary shares pursuant to the exercise of an employee stock option or otherwise as compensation; or
- persons holding shares in connection with a trade or business conducted outside of the United States.

If an entity that is classified as a partnership for U.S. federal income tax purposes holds ordinary shares, the U.S. federal income tax treatment of a partner will generally depend on the status of the partner and the activities of the partnership. Partnerships holding ordinary shares and partners in such partnerships should consult their tax advisers as to their particular U.S. federal income tax consequences of holding and disposing of the ordinary shares.

This discussion is based on the U.S. Internal Revenue Code of 1986, as amended, or the Code, administrative pronouncements, judicial decisions, and final, temporary and proposed Treasury regulations, all as of the date hereof, any of which is subject to change, possibly with retroactive effect.

A “U.S. Holder” is a holder who, for U.S. federal income tax purposes, is a beneficial owner of ordinary shares who is:

- an individual who is a citizen or resident of the United States;
- a corporation, or other entity taxable as a corporation, created or organized in or under the laws of the United States, any state therein or the District of Columbia;
- an estate whose income is includible in gross income for U.S. federal income tax purposes regardless of its source; or
- a trust if (1) a U.S. court is able to exercise primary supervision over the administration of the trust and one or more U.S. persons have authority to control all substantial decisions of the trust or (2) the trust has a valid election in effect under applicable Treasury Regulations to be treated as a U.S. person.

U.S. Holders should consult their tax advisers concerning the U.S. federal, state, local and foreign tax consequences of owning and disposing of ordinary shares in their particular circumstances.

Passive Foreign Investment Company Rules

We expect to be a passive foreign investment company, or PFIC, for our current taxable year and for the foreseeable future. In addition, we may, directly or indirectly, hold equity interests in other PFICs, or Lower-tier PFICs. In general, a non-U.S. corporation will be considered a PFIC for any taxable year in which (1) 75% or more of its gross income consists of passive income or (2) 50% or more of the average quarterly value of its assets consists of assets that produce, or are held for the production of, passive income. For purposes of the above calculations, a non-U.S. corporation that directly or indirectly owns at least 25% by value of the shares of another corporation is treated as if it held its proportionate share of the assets of the other corporation and received directly its proportionate share of the income of the other corporation. Passive income generally includes dividends, interest, rents, royalties and capital gains.

We must determine our PFIC status annually based on tests which are factual in nature, and our status will depend on our income, assets and activities each year.

Under attribution rules, if we are a PFIC, U.S. Holders will be deemed to own their proportionate shares of Lower-tier PFICs and will be subject to U.S. federal income tax according to the rules described in the following paragraphs on (1) certain distributions by a Lower-tier PFIC and (2) a disposition of shares of a Lower-tier PFIC, in each case as if the U.S. Holder held such shares directly, even though holders have not received the proceeds of those distributions or dispositions directly.

If we are a PFIC for any taxable year during which a U.S. Holder holds our shares, the U.S. Holder may be subject to certain adverse tax consequences. Unless a holder makes a timely “mark-to-market” election or “qualified electing fund” election each as discussed below, gain recognized on a disposition (including, under certain circumstances, a pledge) of ordinary shares by the U.S. Holder, or on an indirect disposition of shares of a Lower-tier PFIC, will be allocated ratably over the U.S. Holder’s holding period for the shares. The amounts allocated to the taxable year of disposition and to years before we became a PFIC will be taxed as ordinary income. The amounts allocated to each other taxable year will be subject to tax at the highest rate in effect for that taxable year for individuals or corporations, as appropriate, and an interest charge will be imposed on the tax attributable to the allocated amounts. Further, to the extent that any distribution received by a U.S.

Holder on our ordinary shares (or a distribution by a Lower-tier PFIC to its shareholder that is deemed to be received by a U.S. Holder) exceeds 125% of the average of the annual distributions on the shares received during the preceding three years or the U.S. Holder's holding period, whichever is shorter, the distribution will be subject to taxation in the same manner as gain, described immediately above and lower rates of taxation applicable to long-term capital gains with respect to dividends paid to certain non-corporate U.S. Holders would not apply.

If we are a PFIC for any year during which a U.S. Holder holds ordinary shares, we generally will continue to be treated as a PFIC with respect to the holder for all succeeding years during which the U.S. Holder holds ordinary shares, even if we cease to meet the threshold requirements for PFIC status. U.S. Holders should consult their tax advisers regarding the potential availability of a "deemed sale" election that would allow them to eliminate this continuing PFIC status under certain circumstances.

If the ordinary shares are "regularly traded" on a "qualified exchange," a U.S. Holder may make a mark-to-market election that would result in tax treatment different from the general tax treatment for PFICs described above. The ordinary shares will be treated as "regularly traded" in any calendar year in which more than a *de minimis* quantity of the ordinary shares is traded on a qualified exchange on at least 15 days during each calendar quarter. The NASDAQ Global Select Market, to which we intend to apply for the listing of our ordinary shares, is a qualified exchange for this purpose. U.S. Holders should consult their tax advisers regarding the availability and advisability of making a mark-to-market election in their particular circumstances. In particular, U.S. Holders should consider carefully the impact of a mark-to-market election with respect to their ordinary shares given that we may have Lower-tier PFICs for which a mark-to-market election may not be available.

If a U.S. Holder makes the mark-to-market election, the holder generally will recognize as ordinary income any excess of the fair market value of the ordinary shares at the end of each taxable year over their adjusted tax basis, and will recognize an ordinary loss in respect of any excess of the adjusted tax basis of the ordinary shares over their fair market value at the end of the taxable year (but only to the extent of the net amount of income previously included as a result of the mark-to-market election). If a U.S. Holder makes the election, the holder's tax basis in the ordinary shares will be adjusted to reflect the income or loss amounts recognized. Any gain recognized on the sale or other disposition of ordinary shares in a year when we are a PFIC will be treated as ordinary income and any loss will be treated as an ordinary loss (but only to the extent of the net amount of income previously included as a result of the mark-to-market election). Distributions paid on ordinary shares will be treated as discussed below under "—Taxation of Distributions."

Alternatively, a U.S. Holder can make an election, if we provide the necessary information, to treat us and each Lower-tier PFIC as a qualified electing fund, or a QEF Election, in the first taxable year that we are treated as a PFIC with respect to the holder. A U.S. Holder must make the QEF Election for each PFIC by attaching a separate properly completed IRS Form 8621 for each PFIC to the holder's timely filed U.S. federal income tax return. U.S. Holders should be aware that there can be no assurances that we will satisfy the record keeping requirements that apply to a QEF, or that we will supply U.S. Holders with information that such U.S. Holders are required to report under the QEF rules, in the event that we are a PFIC. Thus, U.S. Holders may not be able to make a QEF Election with respect to their ordinary shares. Further, no assurance can be given that such QEF information will be available for any Lower-tier PFIC. Each U.S. Holder should consult its own tax advisers regarding the availability of, and procedure for making, a QEF Election.

If a U.S. Holder makes a QEF Election with respect to a PFIC, the holder will be taxed on a current basis on its pro rata share of the PFIC's ordinary earnings and net capital gain (at ordinary income and capital gain rates, respectively) for each taxable year that the entity is classified as a PFIC and for which the QEF election is in place and properly maintained. If a U.S. Holder makes a QEF

Election with respect to us, any distributions paid by us out of our earnings and profits that were previously included in the holder's income under the QEF Election would not be taxable to the holder. A U.S. Holder will increase its tax basis in its ordinary shares by an amount equal to any income included under the QEF Election and will decrease its tax basis by any amount distributed on the ordinary shares that is not included in the holder's income. In addition, a U.S. Holder will recognize capital gain or loss on the disposition of ordinary shares in an amount equal to the difference between the amount realized and the holder's adjusted tax basis in the ordinary shares. U.S. Holders should note that if they make QEF Elections with respect to us and Lower-tier PFICs, they may be required to pay U.S. federal income tax with respect to their ordinary shares for any taxable year significantly in excess of any cash distributions received on the shares for such taxable year. U.S. Holders should consult their tax advisers regarding making QEF Elections in their particular circumstances.

Furthermore, as discussed below, if we were a PFIC or, with respect to a particular U.S. Holder, were treated as a PFIC for the taxable year in which we paid a dividend or the prior taxable year, the 20% preferential tax rate with respect to dividends paid to certain non-corporate U.S. Holders would not apply.

If we were a PFIC for any taxable year during which a U.S. Holder held ordinary shares, such U.S. Holder would be required to file an annual information report with such U.S. Holder's U.S. Federal income tax return on IRS Form 8621.

U.S. Holders should consult their tax advisers concerning our PFIC status and the tax considerations relevant to an investment in a PFIC.

Taxation of Distributions

Subject to the passive foreign investment company rules described above, distributions paid on ordinary shares, other than certain pro rata distributions of ordinary shares, will be treated as dividends to the extent paid out of our current or accumulated earnings and profits (as determined under U.S. federal income tax principles). Because we do not maintain calculations of our earnings and profits under U.S. federal income tax principles, it is expected that distributions generally will be reported to U.S. Holders as dividends. The amount of a dividend will include any amounts withheld by us in respect of Irish taxes. The amount of the dividend will be treated as foreign-source dividend income to U.S. Holders and will not be eligible for the dividends-received deduction generally available to U.S. corporations under the Code. Dividends will be included in a U.S. Holder's income on the date of the U.S. Holder's receipt of the dividend. The amount of any dividend income paid in Euros will be the U.S. dollar amount calculated by reference to the exchange rate in effect on the date of receipt, regardless of whether the payment is in fact converted into U.S. dollars. If the dividend is converted into U.S. dollars on the date of receipt, a U.S. Holder should not be required to recognize foreign currency gain or loss in respect of the dividend income. A U.S. Holder may have foreign currency gain or loss if the dividend is converted into U.S. dollars after the date of receipt, which will be "U.S. source" ordinary income or loss.

Dividends paid by us may be taxable to a non-corporate U.S. Holder at the special reduced rate normally applicable to long-term capital gains, provided we are not a PFIC in the taxable year in which the dividends are received or in the preceding taxable year, so long as certain holding period requirements are met. As discussed above under "Passive Foreign Investment Company Rules," we expect to be a PFIC and, as a result, the special reduced rate is unlikely to be available with respect to dividends paid by us.

Subject to applicable limitations, some of which vary depending upon the U.S. Holder's circumstances, Irish income taxes withheld from dividends on ordinary shares may be creditable against the U.S. Holder's U.S. federal income tax liability. The rules governing foreign tax credits are complex, and U.S. Holders should consult their tax advisers regarding the creditability of foreign taxes in their

particular circumstances. In lieu of claiming a foreign tax credit, U.S. Holders may, at their election, deduct foreign taxes, including the Irish tax, in computing their taxable income, subject to generally applicable limitations under U.S. law. An election to deduct foreign taxes instead of claiming foreign tax credits applies to all foreign taxes paid or accrued in the taxable year.

Sale or Other Disposition of Ordinary Shares

Subject to the passive foreign investment company rules described above, for U.S. federal income tax purposes, gain or loss realized on the sale or other disposition of ordinary shares will be capital gain or loss, and will be long-term capital gain or loss if the U.S. Holder held the ordinary shares for more than one year. The amount of the gain or loss will equal the difference between the U.S. Holder's tax basis in the ordinary shares disposed of and the amount realized on the disposition, in each case as determined in U.S. dollars. This gain or loss will generally be U.S.-source gain or loss for foreign tax credit purposes.

Net Investment Income Tax

U.S. Holders that are individuals or estates or trusts that do not fall into a special class of trusts that is exempt from such tax, will be required to pay an additional 3.8% tax on the lesser of (1) the U.S. Holder's "net investment income" for the relevant taxable year and (2) the excess of the U.S. Holder's modified adjusted gross income for the taxable year over a certain threshold (which in the case of individuals will be between US \$125,000 and US \$250,000, depending on the individual's circumstances). A U.S. Holder's "net investment income" will generally include, among other things, dividends and capital gains. Such tax will apply to dividends and to capital gains from the sale or other disposition of the ordinary shares, unless derived in the ordinary course of the conduct of a trade or business (other than a trade or business that consists of certain passive or trading activities). Special rules apply and certain elections are available for certain U.S. Holders that are subject to the 3.8% tax on net investment income and hold shares in a PFIC. Potential investors should consult with their own tax advisers regarding the application of the net investment income tax to them as a result of their investment in our ordinary shares.

Information Reporting and Backup Withholding

Payments of dividends and sales proceeds that are made within the United States or through certain U.S.-related financial intermediaries generally are subject to information reporting, and may be subject to backup withholding, unless (1) the U.S. Holder is a corporation or other exempt recipient or (2) in the case of backup withholding, the U.S. Holder provides a correct taxpayer identification number and certifies that it is not subject to backup withholding.

Backup withholding is not an additional tax. Amounts withheld as backup withholding may be credited against such holder's U.S. federal income tax liability, and such holder may obtain a refund of any excess amounts withheld under the backup withholding rules by filing an appropriate claim for refund with the IRS and furnishing any required information in a timely manner. U.S. Holders of ordinary shares should consult their tax advisers regarding the application of the U.S. information reporting and backup withholding rules.

Information With Respect to Foreign Financial Assets

Certain U.S. Holders who are individuals (and, under proposed regulations, certain entities) may be required to report information relating to an interest in our ordinary shares, subject to certain exceptions (including an exception for ordinary shares held in accounts maintained by certain U.S. financial institutions). U.S. Holders should consult their tax advisers regarding the effect, if any, of this requirement on their ownership and disposition of the ordinary shares.

UNDERWRITING

Stifel, Nicolaus & Company, Incorporated is acting as representative of each of the underwriters named below. Subject to the terms and conditions set forth in an underwriting agreement among us and the underwriters, we have agreed to sell to the underwriters, and each of the underwriters has agreed, severally and not jointly, to purchase from us, the number of ordinary shares set forth opposite its name below.

Underwriter	Number of Ordinary Shares
Stifel, Nicolaus & Company, Incorporated	1,562,500
JMP Securities LLC	500,000
Roth Capital Partners, LLC	312,500
Arctic Securities AS	125,000
Total	2,500,000

Subject to the terms and conditions set forth in the underwriting agreement, the underwriters will agree, severally and not jointly, to purchase all of the ordinary shares sold under the underwriting agreement if any of these shares are purchased. If an underwriter defaults, the underwriting agreement will provide that the purchase commitments of the non-defaulting underwriters may be increased or the underwriting agreement may be terminated.

We will agree to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act, or to contribute to payments the underwriters may be required to make in respect of those liabilities.

The underwriters are offering the ordinary shares, subject to prior sale, when, as and if issued to and accepted by them, subject to approval of legal matters by their counsel, including the validity of the ordinary shares, and other conditions contained in the underwriting agreement, such as the receipt by the underwriters of officer's certificates and legal opinions. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

Commissions and Discounts

The representative has advised us that the underwriters propose initially to offer the ordinary shares to the public at the public offering price set forth on the cover page of this prospectus and to dealers at that price less a concession not in excess of \$0.42 per ordinary share. After the initial offering, the public offering price, concession or any other term of the offering may be changed.

The following table shows the public offering price, underwriting discount and proceeds before expenses to us. The information assumes either no exercise or full exercise by the underwriters of their option to purchase additional ordinary shares.

	Per Share	Without Option	With Option
Public offering price	\$10.00	\$25,000,000	\$28,750,000
Underwriting discount	\$ 0.70	\$ 1,750,000	\$ 2,012,500
Proceeds, before expenses, to Strongbridge . . .	\$ 9.30	\$23,250,000	\$26,737,500

The expenses of this offering, not including the underwriting discount, are estimated at approximately \$4.0 million and are payable by us. We have also agreed to reimburse the underwriters for their expenses relating to clearance of this offering with the Financial Industry Regulatory Authority, or FINRA, in an amount up to \$25,000.

Pursuant to an advisory services agreement between Arctic Securities AS and us, we will pay Arctic Securities AS an aggregate amount of \$50,000 in fees and expenses. In accordance with FINRA Rule 5110, the underwriters' reimbursed FINRA counsel fee and the \$50,000 in fees and expenses received by Arctic Securities AS are deemed underwriting compensation for this offering. Arctic Securities AS, has not and will not make any offer of the ordinary shares to persons within the United States.

Option to Purchase Additional Ordinary Shares

We have granted an option to the underwriters, exercisable for 30 days after the date of this prospectus, to purchase up to 375,000 additional ordinary shares at the public offering price, less the underwriting discount. If the underwriters exercise this option, each will be obligated, subject to conditions contained in the underwriting agreement, to purchase a number of additional ordinary shares proportionate to that underwriter's initial amount reflected in the above table.

No Sales of Similar Securities

We, our executive officers and directors and certain our other existing security holders have agreed not to sell or transfer any ordinary shares or securities convertible into, exchangeable for, exercisable for, or repayable with ordinary shares, for up to 180 days after the date of this prospectus without first obtaining the written consent of Stifel, Nicolaus & Company, Incorporated. Specifically, we and these other persons have agreed, with certain limited exceptions, not to directly or indirectly:

- offer, pledge, sell or contract to sell any ordinary shares,
- sell any option or contract to purchase any ordinary shares,
- purchase any option or contract to sell any ordinary shares,
- grant any option, right or warrant for the sale of any ordinary shares,
- lend or otherwise dispose of or transfer any ordinary shares,
- request or demand that we file a registration statement related to the ordinary shares, or
- enter into any swap or other agreement that transfers, in whole or in part, the economic consequence of ownership of any ordinary shares whether any such swap or transaction is to be settled by delivery of shares or other securities, in cash or otherwise.

This lock-up provision applies to ordinary shares and to securities convertible into or exchangeable or exercisable for or repayable with ordinary shares. It also applies to ordinary shares owned now or acquired later by the person executing the agreement or for which the person executing the agreement later acquires the power of disposition.

The NASDAQ Global Select Market Listing

Our ordinary shares have been approved for listing on The NASDAQ Global Select Market under the symbol "SBBP."

Our ordinary shares are currently quoted on the NOTC A-list in Norway. The initial public offering price has been determined through negotiations between us and the representative. In addition to prevailing market conditions, other factors to be considered in determining the initial public offering price are:

- the valuation multiples of publicly traded companies that the representative believes to be comparable to us;
- our financial information;

- the history of, and the prospects for, our company and the industry in which we compete;
- an assessment of our management, its past and present operations, and the prospects for, and timing of, our future revenues;
- the present state of our development; and
- the above factors in relation to market values and various valuation measures of other companies engaged in activities similar to ours.

An active trading market for our ordinary shares in the United States may not develop. It is also possible that after this offering our ordinary shares will not trade in the public market at or above the initial public offering price.

The underwriters do not expect to sell more than 5% of our ordinary shares in the aggregate to accounts over which they exercise discretionary authority.

Price Stabilization, Short Positions and Penalty Bids

Until the distribution of the ordinary shares is completed, SEC rules may limit underwriters and selling group members from bidding for and purchasing the ordinary shares. However, the representative may engage in transactions that stabilize the price of the ordinary shares, such as bids or purchases to peg, fix or maintain that price.

In connection with this offering, the underwriters may purchase and sell the ordinary shares in the open market. These transactions may include short sales, purchases on the open market to cover positions created by short sales and stabilizing transactions. Short sales involve the sale by the underwriters of a greater number of ordinary shares than they are required to purchase in this offering. “Covered” short sales are sales made in an amount not greater than the underwriters’ option to purchase additional ordinary shares described above. The underwriters may close out any covered short position by either exercising their option to purchase additional ordinary shares or purchasing ordinary shares in the open market. In determining the source of shares to close out the covered short position, the underwriters will consider, among other things, the price of ordinary shares available for purchase in the open market as compared to the price at which they may purchase ordinary shares through the option granted to them. “Naked” short sales are sales in excess of such option. The underwriters must close out any naked short position by purchasing ordinary shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the ordinary shares in the open market after pricing that could adversely affect investors who purchase in this offering. Stabilizing transactions consist of various bids for or purchases of ordinary shares made by the underwriters in the open market prior to the completion of the offering.

The underwriters may also impose a penalty bid. This occurs when a particular underwriter repays to the underwriters a portion of the underwriting discount received by it because the representative has repurchased ordinary shares sold by or for the account of such underwriter in stabilizing or short covering transactions.

Similar to other purchase transactions, the underwriters’ purchases to cover the syndicate short sales may have the effect of raising or maintaining the market price of the ordinary shares or preventing or retarding a decline in the market price of the ordinary shares. As a result, the price of the ordinary shares may be higher than the price that might otherwise exist in the open market. The underwriters may conduct these transactions on The NASDAQ Global Select Market, in the over-the-counter market or otherwise.

Neither we nor any of the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of the

ordinary shares. In addition, neither we nor any of the underwriters make any representation that the representative will engage in these transactions or that these transactions, once commenced, will not be discontinued without notice.

Electronic Distribution

In connection with this offering, certain of the underwriters or securities dealers may distribute prospectuses by electronic means, such as e-mail.

Relationship with Locust Walk

We have engaged Locust Walk Securities LLC, or Locust Walk, a FINRA member, to serve as our financial advisor in connection with this offering. We expect to pay Locust Walk, upon the completion of this offering, aggregate fees of \$750,000 for its services. The services provided by Locust Walk included customary business and financial analysis, assistance in preparing information materials regarding the offering, coordinating diligence sessions and advising us with respect to the marketing and structuring of this offering. Locust Walk is not acting as an underwriter and will not sell or offer to sell any securities and will not identify, solicit or engage directly with potential investors. In addition, Locust Walk will not underwrite or purchase any of the offered securities or otherwise participate in any such undertaking.

Other Relationships

Some of the underwriters and their affiliates have engaged in, and may in the future engage in, investment banking and other commercial dealings in the ordinary course of business with us or our affiliates. They have received, or may in the future receive, customary fees and commissions for these transactions.

In addition, in the ordinary course of their business activities, the underwriters and their affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers. Such investments and securities activities may involve securities and/or instruments of ours or our affiliates. The underwriters and their affiliates may also make investment recommendations and/or publish or express independent research views in respect of such securities or financial instruments and may hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

Certain of our existing shareholders and their affiliates have indicated an interest in purchasing up to an aggregate of \$20.0 million of our ordinary shares in this offering at the initial public offering price per share. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters may determine to sell more, less or no shares in this offering to any of these entities, or any of these entities may determine to purchase more, less or no shares in this offering. The underwriters will receive the same underwriting discount on any ordinary shares purchased by these entities as they will on any other shares sold to the public in this offering.

Notice to Prospective Investors in the European Economic Area

In relation to each Member State of the European Economic Area, or Relevant Member State, no offer of ordinary shares may be made to the public in that Relevant Member State other than:

- to any legal entity which is a qualified investor as defined in the Prospectus Directive;
- to fewer than 100 or, if the Relevant Member State has implemented the relevant provision of the 2010 PD Amending Directive, 150, natural or legal persons (other than qualified

investors as defined in the Prospectus Directive), as permitted under the Prospectus Directive, subject to obtaining the prior consent of the representative; or

- in any other circumstances falling within Article 3(2) of the Prospectus Directive;

provided that no such offer of ordinary shares shall require us or the representative to publish a prospectus pursuant to Article 3 of the Prospectus Directive or supplement a prospectus pursuant to Article 16 of the Prospectus Directive.

Each person in a Relevant Member State who initially acquires any ordinary shares or to whom any offer is made will be deemed to have represented, acknowledged and agreed that it is a “qualified investor” within the meaning of the law in that Relevant Member State implementing Article 2(1)(e) of the Prospectus Directive. In the case of any ordinary shares being offered to a financial intermediary as that term is used in Article 3(2) of the Prospectus Directive, each such financial intermediary will be deemed to have represented, acknowledged and agreed that the ordinary shares acquired by it in the offer have not been acquired on a non-discretionary basis on behalf of, nor have they been acquired with a view to their offer or resale to, persons in circumstances which may give rise to an offer of any ordinary shares to the public other than their offer or resale in a Relevant Member State to qualified investors as so defined or in circumstances in which the prior consent of the representative has been obtained to each such proposed offer or resale.

We, the representative and its affiliates will rely upon the truth and accuracy of the foregoing representations, acknowledgements and agreements.

This document has not been approved by any competent prospectus authority in the European Economic Area, and therefore, has been prepared on the basis that any offer of shares in any Relevant Member State will be made pursuant to an exemption under the Prospectus Directive from the requirement to publish a prospectus for offers of shares. Accordingly any person making or intending to make an offer in that Relevant Member State of shares which are the subject of this offering may only do so in circumstances in which no obligation arises for us or any of the underwriters to publish a prospectus pursuant to Article 3 of the Prospectus Directive in relation to such offer. Neither we nor the underwriters have authorized, nor do they authorize, the making of any offer of shares in circumstances in which an obligation arises for us or the underwriters to publish a prospectus for such offer.

For the purpose of the above provisions, the expression “an offer to the public” in relation to any shares in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and the shares to be offered so as to enable an investor to decide to purchase or subscribe for the shares, as the same may be varied in the Relevant Member State by any measure implementing the Prospectus Directive in the Relevant Member State and the expression “Prospectus Directive” means Directive 2003/71/EC (including the 2010 PD Amending Directive, to the extent implemented in the Relevant Member States) and includes any relevant implementing measure in the Relevant Member State and the expression “2010 PD Amending Directive” means Directive 2010/73/EU.

Notice to Prospective Investors in Norway

This document has not been approved by, registered with or passported to the Norwegian Financial Supervisory Authority or the Norwegian Register of Business Enterprises pursuant to Chapter 7 of the Norwegian Securities Trading Act of 29 June 2007 as amended, or the Norwegian Securities Act.

The ordinary shares may not be offered or sold directly or indirectly to prospective investors in Norway except to (i) selected investors who are Professional Investors under the Norwegian Securities Act, (ii) selected investors who are fewer than 150 natural or legal persons (subject to obtaining prior

consent of the representative), (iii) selected investors subject to a minimum subscription and allocation amount per investor of the U.S. dollar equivalent of 100,000 Euros, and (iv) otherwise in circumstances which will not trigger the requirement to prepare and file a prospectus in connection with the offer of the ordinary shares under the Norwegian Securities Act.

This document is only and exclusively addressed to the addressees in Norway and cannot be distributed, offered or presented, either directly or indirectly to other persons or entities domiciled in Norway without the consent of the representative.

Prospective investors are advised to seek legal advice to ensure that they are classified as Professional Investors under the Norwegian Securities Act or are otherwise in circumstances which will not trigger a prospectus requirement under the Norwegian Securities Act.

Notice to Prospective Investors in the United Kingdom

In addition, in the United Kingdom, this document is being distributed only to, and is directed only at, and any offer subsequently made may only be directed at persons who are “qualified investors” (as defined in the Prospectus Directive) (1) who have professional experience in matters relating to investments falling within Article 19 (5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended, or the Order, and/or (2) who are high net worth companies (or persons to whom it may otherwise be lawfully communicated) falling within Article 49(2)(a) to (d) of the Order (all such persons together being referred to as “relevant persons”). This document must not be acted on or relied on in the United Kingdom by persons who are not relevant persons. In the United Kingdom, any investment or investment activity to which this document relates is only available to, and will be engaged in with, relevant persons.

Notice to Prospective Investors in Switzerland

The ordinary shares may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange, or the SIX, or on any other stock exchange or regulated trading facility in Switzerland. This document has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering or marketing material relating to the shares or this offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering or marketing material relating to this offering, as or the ordinary shares have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of shares will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA, and the offer of shares has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes, or CISA. The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of shares.

Notice to Prospective Investors in Canada

The ordinary shares may be sold only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 Prospectus Exemptions or subsection 73.3(1) of the Securities Act (Ontario), and are permitted clients, as defined in National Instrument 31-103 Registration Requirements, Exemptions and Ongoing Registrant Obligations. Any resale of the ordinary shares must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 (or, in the case of securities issued or guaranteed by the government of a non-Canadian jurisdiction, section 3A.4) of National Instrument 33-105 Underwriting Conflicts (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

Notice to Prospective Investors in the Dubai International Financial Centre

This prospectus relates to an Exempt Offer in accordance with the Offered Securities Rules of the Dubai Financial Services Authority, or DFSA. This prospectus is intended for distribution only to persons of a type specified in the Offered Securities Rules of the DFSA. It must not be delivered to, or relied on by, any other person. The DFSA has no responsibility for reviewing or verifying any documents in connection with Exempt Offers. The DFSA has not approved this prospectus nor taken steps to verify the information set forth herein and has no responsibility for the prospectus. The shares to which this prospectus relates may be illiquid and/or subject to restrictions on their resale. Prospective purchasers of the shares offered should conduct their own due diligence on the shares. If you do not understand the contents of this prospectus you should consult an authorized financial advisor.

Notice to Prospective Investors in Australia

No placement document, prospectus, product disclosure statement or other disclosure document has been lodged with the Australian Securities and Investments Commission, or ASIC, in relation to the offering. This document does not constitute a prospectus, product disclosure statement or other disclosure document under the Corporations Act 2001, or the Corporations Act, and does not purport to include the information required for a prospectus, product disclosure statement or other disclosure document under the Corporations Act.

Any offer in Australia of the shares may only be made to persons, or the Exempt Investors, who are "sophisticated investors" (within the meaning of section 708(8) of the Corporations Act), "professional investors" (within the meaning of section 708(11) of the Corporations Act) or otherwise pursuant to one or more exemptions contained in section 708 of the Corporations Act so that it is lawful to offer the shares without disclosure to investors under Chapter 6D of the Corporations Act.

The shares applied for by Exempt Investors in Australia must not be offered for sale in Australia in the period of 12 months after the date of allotment under this offering, except in circumstances where disclosure to investors under Chapter 6D of the Corporations Act would not be required pursuant to an exemption under section 708 of the Corporations Act or otherwise or where the offer is pursuant to a disclosure document which complies with Chapter 6D of the Corporations Act. Any person acquiring shares must observe such Australian on-sale restrictions.

This prospectus contains general information only and does not take account of the investment objectives, financial situation or particular needs of any particular person. It does not contain any securities recommendations or financial product advice. Before making an investment decision, investors need to consider whether the information in this prospectus is appropriate to their needs, objectives and circumstances, and, if necessary, seek expert advice on those matters.

Notice to Prospective Investors in Hong Kong

The ordinary shares have not been offered or sold and will not be offered or sold in Hong Kong, by means of any document, other than (1) to “professional investors” as defined in the Securities and Futures Ordinance (Cap. 571) of Hong Kong and any rules made under that Ordinance or (2) in other circumstances which do not result in the document being a “prospectus” as defined in the Companies Ordinance (Cap. 32) of Hong Kong or which do not constitute an offer to the public within the meaning of that Ordinance. No advertisement, invitation or document relating to the shares has been or may be issued or has been or may be in the possession of any person for the purposes of issue, whether in Hong Kong or elsewhere, which is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to shares which are or are intended to be disposed of only to persons outside Hong Kong or only to “professional investors” as defined in the Securities and Futures Ordinance and any rules made under that Ordinance.

Notice to Prospective Investors in Japan

The ordinary shares have not been and will not be registered under the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948, as amended) and, accordingly, will not be offered or sold, directly or indirectly, in Japan, or for the benefit of any Japanese Person or to others for re-offering or resale, directly or indirectly, in Japan or to any Japanese Person, except in compliance with all applicable laws, regulations and ministerial guidelines promulgated by relevant Japanese governmental or regulatory authorities in effect at the relevant time. For the purposes of this paragraph, “Japanese Person” shall mean any person resident in Japan, including any corporation or other entity organized under the laws of Japan.

Notice to Prospective Investors in Singapore

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of shares may not be circulated or distributed, nor may the shares be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (1) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore, or the SFA, (2) to a relevant person pursuant to Section 275(1), or any person pursuant to Section 275(1A), and in accordance with the conditions specified in Section 275, of the SFA, or (3) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where the shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

- (a) a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or
- (b) a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor,

securities (as defined in Section 239(1) of the SFA) of that corporation or the beneficiaries’ rights and interest (howsoever described) in that trust shall not be transferred within six months after that

corporation or that trust has acquired the shares pursuant to an offer made under Section 275 of the SFA except:

- (c) to an institutional investor or to a relevant person defined in Section 275(2) of the SFA, or to any person arising from an offer referred to in Section 275(1A) or Section 276(4)(i)(B) of the SFA;
- (d) where no consideration is or will be given for the transfer;
- (e) where the transfer is by operation of law;
- (f) as specified in Section 276(7) of the SFA; or
- (g) as specified in Regulation 32 of the Securities and Futures (Offers of Investments) (Shares and Debentures) Regulations 2005 of Singapore.

EXPENSES OF THE OFFERING

The following table sets forth the costs and expenses, other than the underwriting discount, payable in connection with the sale and distribution of the securities being registered. All amounts are estimated except the SEC registration fee, the FINRA filing fee and the NASDAQ listing fee. All the expenses below will be paid by us.

<u>Expenses</u>	<u>Amount</u>
SEC registration fee	\$ 2,895
NASDAQ listing fee	125,000
FINRA filing fee	13,438
Printing and engraving expenses	350,000
Legal fees and expenses	1,920,000
Accounting fees and expenses	521,000
Transfer agent and registrar fees and expenses	290,000
Miscellaneous fees and expenses	775,500
Total	<u>\$3,997,833</u>

LEGAL MATTERS

The validity of the ordinary shares and certain other matters of Irish law will be passed upon for us by Arthur Cox, Dublin, Ireland. Certain matters of U.S. federal and New York State law will be passed upon for us by Reed Smith LLP, New York, New York. Cooley LLP is acting as U.S. counsel for the underwriters in connection with this offering.

EXPERTS

The balance sheet of Strongbridge Biopharma plc (formerly Cortendo plc), as of May 26, 2015, appearing in this prospectus and registration statement has been audited by Ernst & Young AB, an independent registered public accounting firm, as set forth in their report thereon appearing elsewhere herein, and is included in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

The consolidated financial statements of Cortendo AB at December 31, 2013 and 2014, and for each of the two years in the period ended December 31, 2014, appearing in this prospectus and registration statement have been audited by Ernst & Young AB, an independent registered public accounting firm, as set forth in their report thereon appearing elsewhere herein, and are included in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

The registered business address of Ernst & Young AB is 401 82 Gothenburg, Sweden.

The financial statements of Aspireo Pharmaceuticals Limited as of December 31, 2013 and 2014, and January 1, 2013 and for each of the two years in the period ended December 31, 2014, appearing in this prospectus and registration statement have been audited by Kost Forer Gabbay & Kasierer, an independent registered public accounting firm, as set forth in their report thereon appearing elsewhere herein, and are included in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

ENFORCEMENT OF CIVIL LIABILITIES

Certain of our directors and executive officers may be nonresidents of the United States. All or a substantial portion of the assets of such nonresident persons and of our company are located outside the United States. As a result, it may not be possible to effect service of process within the United States upon such persons or our company, or to enforce against such persons or Strongbridge in U.S. Courts judgments obtained in such courts predicated upon the civil liability provisions of the federal securities laws of the United States. We have been advised by our Irish counsel that there is doubt as to the enforceability in Ireland against our company and our executive officers and directors who are non-residents of the United States, in original actions or in actions for enforcement of judgments of U.S. Courts, of liabilities predicated solely upon the securities laws of the United States.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the U.S. Securities and Exchange Commission a registration statement (including amendments and exhibits to the registration statement) on Form F-1 under the Securities Act. This prospectus, which is part of the registration statement, does not contain all of the information set forth in the registration statement and the exhibits and schedules to the registration statement. For further information, we refer you to the registration statement and the exhibits and schedules filed as part of the registration statement. If a document has been filed as an exhibit to the registration statement, we refer you to the copy of the document that has been filed. Each statement in this prospectus relating to a document filed as an exhibit is qualified in all respects by the filed exhibit.

Upon completion of this offering, we will become subject to the informational requirements of the Exchange Act. Accordingly, we will be required to file reports and other information with the SEC, including annual reports on Form 20-F and reports on Form 6-K. You may inspect and copy reports and other information filed with the SEC at the Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. Information on the operation of the Public Reference Room may be obtained by calling the SEC at 1-800-SEC-0330. In addition, the SEC maintains an Internet website that contains reports and other information about issuers, like us, that file electronically with the SEC. The address of that website is www.sec.gov.

As a foreign private issuer, we are exempt under the Exchange Act from, among other things, the rules prescribing the furnishing and content of proxy statements, and our executive officers, directors and principal shareholders are exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act. In addition, we will not be required under the Exchange Act to file periodic reports and financial statements with the SEC as frequently or as promptly as U.S. companies whose securities are registered under the Exchange Act.

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CORTENDO AB

(Predecessor of STRONGBRIDGE BIOPHARMA plc)

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Report of independent registered public accounting firm

The Board of Directors and Shareholders of Strongbridge Biopharma plc

We have audited the accompanying balance sheet of Strongbridge Biopharma plc (formerly Cortendo plc) as of May 26, 2015. This balance sheet is the responsibility of the Company's management. Our responsibility is to express an opinion on this balance sheet based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the balance sheet referred to above presents fairly, in all material respects, the financial position of Strongbridge Biopharma plc at May 26, 2015, in conformity with U.S. generally accepted accounting principles.

/s/ Ernst & Young AB

Gothenburg, Sweden

August 17, 2015

Strongbridge Biopharma plc (formerly Cortendo plc)
Balance Sheet
As of May 26, 2015 (date of inception)
(In thousands, except share and per share data)

	<u>May 26,</u> <u>2015</u>
Total assets	—
	<u>—</u>
Total liabilities	—
	<u>—</u>
Stockholders' equity:	
Ordinary Shares (\$1.098 par value, 40,000 shares authorized, issued and outstanding)	44
Receivable from shareholder	(44)
Total stockholders' equity	<u>—</u>
Total liabilities and stockholders' equity	<u>\$—</u>

See accompanying notes to this balance sheet.

Strongbridge Biopharma plc (formerly Cortendo plc)

Balance Sheet

As of May 26, 2015 (date of inception)

(In thousands, except share and per share data)

1. Overview

1.1. General information

Strongbridge Biopharma plc (formerly Cortendo plc) (“Strongbridge”, or the “Company”), formerly known as Cortendo plc, was incorporated in Ireland on May 26, 2015 with registered number 562659 as a public limited company under the Companies Act 2014 and is domiciled in Ireland.

On August 7, 2015, Strongbridge made an exchange offer to acquire any and all issued ordinary shares of Cortendo AB in exchange for beneficial interests in ordinary shares of Strongbridge in the form of Norwegian depositary receipts and, as the case may be, Swedish depositary receipts. Currently, Strongbridge has no operations other than in connection with the exchange offer and no material assets or liabilities. If the exchange offer is successful, Strongbridge will become the parent company of Cortendo AB. Strongbridge has no employees as of May 26, 2015.

2. Significant accounting policies

2.1. Basis of preparation

The accompanying financial statements of the Company have been prepared in accordance with generally accepted accounting principles in the United States (U.S. GAAP) and are presented in U.S. dollars. Separate statements of operation, stockholders equity and cash flow have not been presented in the financial statements because there have been no operations of the Company at the balance sheet date.

3. Share capital

On incorporation (May 26, 2015) the authorized and issued share capital of Strongbridge Biopharma plc was 40,000 ordinary shares with a nominal value of €1.00 per share (US \$ \$1.098 as of May 26, 2015).

4. Subsequent Events

On August 7, 2015, the authorised share capital of the Company was amended by: (i) the cancellation of 960,000 ordinary shares with a nominal value of €1.00 per share, (ii) the creation of 600,000,000 ordinary shares with a nominal value of US\$0.01 per share, (iii) the creation of 100,000,000 preferred shares with a nominal value of US\$0.01 per share and (iv) the redesignation of 40,000 ordinary shares with a nominal value of €1.00 per share into deferred ordinary shares with a nominal value of €1.00 per share.

On August 10, 2015, the Company issued one ordinary share with a nominal value of US\$0.01 to Stichting Cortendo, a foundation incorporated under Dutch law on behalf of Cortendo AB, as the sole shareholder of Strongbridge Biopharma plc.

Other than the amendments to the authorised share capital of the Company and the issuance of one ordinary share to Stichting Cortendo, there have been no material events after the end of the reporting period through the date these separate financial statements were issued which would require disclosure in or adjustment to these separate financial statements.

Report of Independent Registered Public Accounting Firm

The Board of Directors and Shareholders of Cortendo AB

We have audited the accompanying consolidated balance sheets of Cortendo AB as of December 31, 2014 and 2013, and the related consolidated statements of operations, shareholders' equity and cash flows for each of the two years in the period ended December 31, 2014. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Cortendo AB at December 31, 2014 and 2013, and the consolidated results of its operations and its cash flows for each of the two years in the period ended December 31, 2014, in conformity with U.S. generally accepted accounting principles.

/s/ Ernst & Young AB

Gothenburg, Sweden

August 17, 2015 except for Note 1, as to which the date is September 9, 2015

CORTENDO AB
(Predecessor of STRONGBRIDGE BIOPHARMA plc)
Consolidated Balance Sheets
(In thousands, except share and per share data)

	<u>As of December 31,</u>	
	<u>2013</u>	<u>2014</u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 14,897	\$ 15,632
Prepaid expenses and other current assets	226	598
Total current assets	<u>15,123</u>	<u>16,230</u>
Property and equipment, net	6	21
In-process research and development	5,228	5,228
Goodwill	2,200	2,200
Other assets	12	10
Total assets	<u>\$ 22,569</u>	<u>\$ 23,689</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 651	\$ 887
Accrued liabilities	827	1,422
Total current liabilities	<u>1,478</u>	<u>2,309</u>
Stock-based liability awards	1,412	1,183
Deferred tax liabilities	1,856	1,376
Total liabilities	<u>4,746</u>	<u>4,868</u>
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Common stock, \$0.01 par value, 100,000,000 and 175,000,000 shares authorized at December 31, 2013 and 2014; 7,939,608 and 9,700,789 shares issued and outstanding at December 31, 2013 and 2014	79	97
Additional paid-in capital	45,273	55,947
Accumulated deficit	(27,553)	(37,223)
Non-controlling interest	24	—
Total stockholders' equity	<u>17,823</u>	<u>18,821</u>
Total liabilities and stockholders' equity	<u>\$ 22,569</u>	<u>\$ 23,689</u>

The accompanying notes are an integral part of these consolidated financial statements.

CORTENDO AB
(Predecessor of STRONGBRIDGE BIOPHARMA plc)
Consolidated Statements of Operations
(In thousands, except share and per share data)

	Year Ended December 31,	
	2013	2014
Operating expenses:		
Research and development	\$ 2,534	\$ 5,844
General and administrative	2,658	4,588
Total operating expenses	<u>5,192</u>	<u>10,432</u>
Operating loss	(5,192)	(10,432)
Other income (expense), net:		
Foreign exchange loss	(570)	(204)
Other income, net	282	486
Total other income (expense), net	<u>(288)</u>	<u>282</u>
Loss before income taxes	(5,480)	(10,150)
Income tax benefit	93	480
Net loss	(5,387)	(9,670)
Net loss attributable to non-controlling interest	92	—
Net loss attributable to Cortendo	<u>\$ (5,295)</u>	<u>\$ (9,670)</u>
Net loss attributable to ordinary shareholders:		
Basic and diluted	<u>\$ (5,295)</u>	<u>\$ (9,670)</u>
Net loss per share attributable to ordinary shareholders:		
Basic and diluted	<u>\$ (0.88)</u>	<u>\$ (1.20)</u>
Weighted-average shares used in computing net loss per share attributable to ordinary shareholders:		
Basic and diluted	<u>6,017,895</u>	<u>8,043,175</u>

The accompanying notes are an integral part of these consolidated financial statements.

CORTENDO AB
(Predecessor of STRONGBRIDGE BIOPHARMA plc)
Consolidated Statements of Shareholders' Equity
(In thousands except share amounts)

	Cortendo AB Shareholders				Non- Controlling Interest	Total Shareholders' Equity
	Ordinary Shares	Ordinary Shares Amount	Additional Paid-In Capital	Accumulated Deficit		
Balance—January 1, 2013	5,076,789	\$51	\$28,465	\$(22,258)	\$ 1,725	\$ 7,983
Net loss	—	—	—	(5,295)	(92)	(5,387)
Shares exchanged for BioPancreate non-controlling interest	336,136	3	1,563	—	(1,609)	(43)
Stock-based compensation	—	—	346	—	—	346
Issuance of shares	<u>2,526,683</u>	<u>25</u>	<u>14,899</u>	<u>—</u>	<u>—</u>	<u>14,924</u>
Balance—December 31, 2013	7,939,608	79	45,273	(27,553)	24	17,823
Net loss	—	—	—	(9,670)	—	(9,670)
Stock-based compensation	—	—	480	—	—	480
Shares exchanged for BioPancreate non-controlling interest	5,272	—	19	—	(24)	(5)
Issuance of shares	<u>1,755,909</u>	<u>18</u>	<u>10,175</u>	<u>—</u>	<u>—</u>	<u>10,193</u>
Balance—December 31, 2014	<u>9,700,789</u>	<u>\$97</u>	<u>\$55,947</u>	<u>\$(37,223)</u>	<u>\$ —</u>	<u>\$18,821</u>

The accompanying notes are an integral part of these consolidated financial statements.

CORTENDO AB
(Predecessor of STRONGBRIDGE BIOPHARMA plc)
Consolidated Statements of Cash Flow
(In thousands)

	Year Ended December 31,	
	2013	2014
Cash flows from operating activities:		
Net loss	\$(5,387)	\$(9,670)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	3	9
Stock-based compensation	748	251
Deferred income tax benefit	(93)	(480)
Foreign exchange loss	570	204
Change in fair value of foreign currency forward contracts	(159)	(279)
Changes in operating assets and liabilities, net of effect of acquisition:		
Accounts payable and accrued liabilities	1,032	831
Prepaid expenses and other current assets	(189)	(370)
Net cash used in operating activities	(3,475)	(9,504)
Cash flows from investing activities:		
Purchase of equipment	(2)	(24)
Net cash used in investing activities	(2)	(24)
Cash flows from financing activities:		
Proceeds from issuance of ordinary shares	14,924	10,193
Net cash provided by financing activities	14,924	10,193
Effect of exchange rate changes on cash and cash equivalents	(455)	70
Net increase in cash and cash equivalents	10,992	735
Cash and cash equivalents—beginning of period	3,905	14,897
Cash and cash equivalents—end of period	\$14,897	\$15,632
Supplemental non-cash investing and financing activities:		
Ordinary shares exchanged for BioPancreate	\$ 2,915	\$ 43

The accompanying notes are an integral part of these consolidated financial statements.

CORTENDO AB
(Predecessor of STRONGBRIDGE BIOPHARMA plc)
Notes to Consolidated Financial Statements

1. Organization

Cortendo AB is a biopharmaceutical company incorporated in Sweden and based in the United States. We are focused on the development, in-licensing, acquisition and eventual commercialization of multiple complementary products and product candidates within the franchises that target rare diseases. Our primary focus to date has been to build our rare endocrine franchise, which includes product candidates for the treatment of Cushing's syndrome and acromegaly, two rare diseases with a high unmet need for innovative treatment options. We also intend to identify and in-license or acquire products or product candidates that will be complementary to our existing rare endocrine franchise or that would form the basis for new rare disease franchises.

Our shares are currently quoted on the Norwegian Over-The-Counter Market, or NOTC,-A list.

Exchange offer

On May 26, 2015, Strongbridge Biopharma plc (then named Cortendo plc) was incorporated under the laws of Ireland.

On August 7, 2015, Strongbridge Biopharma plc made an exchange offer for the outstanding shares of Cortendo AB. The exchange offer was structured as a one-for-one exchange offer in which shareholders of Cortendo AB exchanged their common shares, with a par value of \$0.15, for beneficial interests in ordinary shares of Strongbridge Biopharma plc, with a par value of \$0.01, in the form of Norwegian depository receipts and, as the case may be, Swedish depository receipts, (except for non-accredited investors who hold Cortendo AB shares located in the United States, who were offered cash in an amount equivalent to the value of the Strongbridge Biopharma plc shares such investors would otherwise receive for their Cortendo AB shares exchanged).

The exchange offer was settled on September 8, 2015, and Cortendo AB became a subsidiary with 99.582% of its shares being owned by Strongbridge Biopharma plc. Accordingly, Strongbridge Biopharma plc is a continuation of Cortendo AB, the predecessor, and the consolidated financial statements represent the assets, liabilities and results of operations of Cortendo AB, for all periods presented.

On September 8, 2015, Strongbridge Biopharma plc effected a 1-for-11 reverse stock split of its ordinary shares.

Accordingly, the consolidated financial statements and notes retroactively reflect the capital structure of Strongbridge Biopharma plc after giving effect to the exchange offer and the reverse stock split. With affect from September 8, 2015, the 0.418% of Cortendo AB not owned by Strongbridge Biopharma plc, will be accounted for as a non-controlling interest.

Liquidity

We believe that our cash resources of \$15.6 million at December 31, 2014, together with funds from the share issue of \$26.4 million completed in February of 2015 as well as funds from our share issue of \$33.2 million in June 2015, will be sufficient to allow us to fund our current operating plan for at least the next 12 months. As we continue to incur losses, our transition to profitability is dependent upon the successful development, approval and commercialization of our product candidates and achieving a level of revenues adequate to support our cost structure. We may never achieve profitability, and unless and until we do, we will continue to need to raise additional capital. Our management intends to fund future operations through additional equity offerings, and may seek

CORTENDO AB
(Predecessor of STRONGBRIDGE BIOPHARMA plc)
Notes to Consolidated Financial Statements (Continued)

additional capital through arrangements with strategic partners or from other sources. There can be no assurances, however, that additional funding will be available on terms acceptable to us.

2. Summary of significant accounting policies and basis of presentation

Basis of presentation and principles of consolidation

The accompanying consolidated financial statements include the accounts of our wholly owned subsidiaries, BioPancreate Inc. (Trevose, Pennsylvania, United States), and Cortendo Invest AB (Gothenburg, Sweden). All intercompany balances and transactions have been eliminated in consolidation. These consolidated financial statements have been prepared in conformity with generally accepted accounting principles in the United States (U.S. GAAP). Any reference in these notes to applicable guidance is meant to refer to the authoritative U.S. GAAP as found in the Accounting Standards Codification (ASC) and Accounting Standards Update (ASU) of the Financial Accounting Standards Board (FASB).

For the years ended December 31, 2013 and 2014, we early adopted ASU 2014-10, Development Stage Entities, which removed the concept of a Development Stage Entity from U.S. GAAP, eliminating all incremental reporting requirements, such as providing inception-to-date information, for such entities.

Foreign currency translation

The consolidated financial statements are reported in United States dollars, which is the functional currency of our subsidiaries and Cortendo AB. Transactions in foreign currencies are translated into our functional currency at the rate of exchange prevailing at the date of the transaction. Any monetary assets and liabilities arising from these transactions are translated into our functional currency at exchange rates prevailing at the balance sheet date or on settlement. Resulting gains and losses are recorded in foreign exchange loss in our consolidated statements of operations.

Use of estimates

The preparation of financial statements in conformity with U.S. GAAP requires us to make estimates and assumptions that affect the reported amounts in the financial statements and accompanying notes. We must apply significant judgment in this process. Actual results could materially differ from those estimates.

Segment information

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker, or decision making group, in making decisions on how to allocate resources and assess performance. We view our operations and manage our business in one operating segment. Our material long-lived assets, which consist of in-process research and development, reside in the United States.

Cash and cash equivalents

We consider all short-term highly liquid investments with an original maturity at the date of purchase of three months or less to be cash equivalents. Cash and cash equivalents consist of account balances at banks and money market accounts, respectively.

CORTENDO AB
(Predecessor of STRONGBRIDGE BIOPHARMA plc)
Notes to Consolidated Financial Statements (Continued)

Concentration of credit risk and other risks and uncertainties

Cash deposits in Sweden and Norway for the years ended December 31, 2013 and 2014 of \$14.9 million and \$15.4 million, respectively, are subject to local banking laws and may bear higher or lower risk than cash deposited in the United States. As part of our cash and investment management processes, we perform periodic evaluations of the credit standing of the financial institutions with which we deposit our cash or purchase cash equivalents, and we have not sustained any credit losses from instruments held at these financial institutions.

We are exposed to concentrations of credit risk through the foreign currency forward contracts into which we enter to the extent we have recorded an asset in relation thereto. The counterparties to the agreements relating to our foreign currency forward contracts consist of financial institutions with high credit standing and accordingly we do not believe there is significant risk related to non-performance by these counterparties due to credit risk.

Fair value of financial instruments

Fair value accounting is applied for all financial assets and liabilities and non-financial assets and liabilities that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually).

We are required to disclose information on all assets and liabilities reported at fair value that enables an assessment of the inputs used in determining the reported fair values. FASB ASC Topic 820, Fair Value Measurements and Disclosures (ASC 820), establishes a hierarchy of inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the observable inputs be used when available. Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of us. Unobservable inputs are inputs that reflect our assumptions about the inputs that market participants would use in pricing the asset or liability, and are developed based on the best information available in the circumstances. The fair value hierarchy applies only to the valuation inputs used in determining the reported fair value of the investments and is not a measure of the investment credit quality. The three levels of the fair value hierarchy are described as follows:

Level 1—Valuations based on unadjusted quoted prices in active markets for identical assets or liabilities that we have the ability to access at the measurement date.

Level 2—Valuations based on quoted prices for similar assets or liabilities, or quoted prices in markets that are not active, and for which all significant inputs are observable, either directly or indirectly.

Level 3—Valuations that require inputs that reflect our own assumptions that are both significant to the fair value measurement and unobservable. To the extent that valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment we exercise in determining fair value is greatest for instruments categorized in Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

We enter into foreign currency forward contracts to offset some of the foreign exchange risks we bear on operating expenses that are not denominated in U.S. dollars. These instruments are not

CORTENDO AB
(Predecessor of STRONGBRIDGE BIOPHARMA plc)
Notes to Consolidated Financial Statements (Continued)

entered into for speculative purposes and, although we believe they serve as effective economic hedges, we do not seek to qualify for hedge accounting.

These forward contracts are recorded at fair value on the accompanying consolidated balance sheets as prepaid expenses and other current assets. These forward contracts are measured using observable quoted prices for similar instruments. The outstanding notional amount of our unsettled foreign currency forward contracts as of December 31, 2013 and 2014 was \$10.1 million and \$2.3 million, respectively, and the fair values of those assets were \$159,000 and \$438,000, respectively. The gain recognized in other income, net, for these forward contracts was \$0.2 million and \$0.3 million for the years ended December 31, 2013 and 2014, respectively. These amounts represent the net gain on the forward contracts and do not include changes in the related exposures, which generally offset a portion of the gain on the forward contracts.

Counterparties to these instruments are major financial institutions with credit ratings of investment grade or better and no collateral is required. We believe the risk of incurring any losses on these forward contracts related to credit risk is remote.

Property and equipment, net

Property and equipment, net, consists of office equipment such as furniture, fixtures and computers. Depreciation expense for the years ended December 31, 2013 and 2014 was not significant. The following amortization periods were used for the various classifications of property and equipment, net:

	Amortization Periods
Computer hardware	3-5 years
Computer software	2-5 years
Furniture and fixtures	2-5 years

Business combinations

When acquiring new enterprises over which we obtain control, the acquisition method is applied. Under this method, we identify assets and liabilities of these enterprises and measure them at fair value at the acquisition date. Allowance is made for the tax effect of the adjustments made.

The acquisition consideration for an enterprise consists of the fair value of the consideration paid for the acquired enterprise. Costs that are attributable to the acquisition of the enterprise are recognized in our statements of operations when incurred. We recognize the non-controlling interest at fair value on the acquisition date. The non-controlling interest, which represents the minority ownership of other BioPancreate stockholders, is not remeasured in subsequent periods and is allocated its share of the consolidated net loss. For the period ended December 31, 2013, the allocated loss was \$92,000.

The excess of the consideration transferred, the amount of the non-controlling interest in the acquiree and the acquisition date fair value of previous equity interest in the acquiree over the fair value of the identifiable net assets acquired is recorded as goodwill.

In-process research and development

Purchased identifiable intangible assets with indefinite lives, such as our in-process research and development, are evaluated for impairment annually in accordance with our policy and whenever

CORTENDO AB
(Predecessor of STRONGBRIDGE BIOPHARMA plc)
Notes to Consolidated Financial Statements (Continued)

events or changes in circumstances indicate that it is more likely than not that the fair value of these assets has been reduced.

To test these assets for impairment, we compare the fair value of the asset to its carrying value. The method we use to estimate the fair value measurements of indefinite-lived intangible assets is based on the income approach. For the impairment analysis for the year ended December 31, 2014, significant unobservable inputs used in the income approach valuation method including a discount rate of 15.5%, a royalty rate of 10% and probabilities of product candidate advancement from one clinical trial phase to the next. The probabilities of product candidate advancement we used were based on standalone statistical analysis on a phase-by-phase basis. There is no correlation between the probabilities of advancement in one phase to the probability of advancement in the prior phase. For purposes of our analysis for the year ended December 31, 2014, we have applied the following approximate probabilities of product candidate advancement by phase: 67% probability of advancing from Phase 1 to Phase 2, 37% probability of advancing from Phase 2 to Phase 3, and 64% probability of advancing from Phase 3 to regulatory approval. An increase (decrease) in the estimated royalty rate of 2% assuming no change in discount rates or probability of success rates would result in a significantly higher (lower) fair value measurement. Significant increases in the discount rate up to 31%, assuming no changes in royalty rates and probability of success rates, would result in a significantly lower fair value measurement.

Goodwill

We test goodwill for impairment on an annual basis or whenever events occur that may indicate possible impairment. This analysis requires us to make a series of critical assumptions to (1) evaluate whether any impairment exists and (2) measure the amount of impairment.

Because we have one operating segment, when testing for a potential impairment of goodwill, we are required to estimate the fair value of our business and determine the carrying value. If the estimated fair value is less than the carrying value of our business, then we are required to estimate the fair value of all identifiable assets and liabilities in a manner similar to a purchase price allocation for an acquired business. Only after this process is completed can the goodwill impairment be determined, if any.

When estimating the fair value of our business for the purposes of our annual analysis, we make estimates and judgments about the future cash flows of our businesses. Our cash flow forecasts are based on assumptions that are consistent with the plans and estimates we are using to manage the underlying business.

To estimate the fair value of the business, a market-based approach is applied, utilizing Cortendo's share price on the Norwegian OTC Stock Exchange as well as the price of shares issued in private placements, such as those completed in September 2013 and in October 2014. We did not record a charge for impairment for the years ended December 31, 2013 and 2014.

Research and development expenses

Research and development costs are expensed as incurred. Research and development expenses consist of internal and external expenses. Internal expenses include compensation and related expenses. External expenses include development, clinical trials, report writing and regulatory compliance costs incurred with clinical research organizations and other third-party vendors. At the end of the reporting period, we compare payments made to third-party service providers to the estimated progress toward

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completion of the research or development objectives. Such estimates are subject to change as additional information becomes available. Depending on the timing of payments to the service providers and the progress that we estimate has been made as a result of the service provided, we may record net prepaid or accrued expense relating to these costs. Upfront and milestone payments made to third parties who perform research and development services on our behalf are expensed as services are rendered.

Stock-based compensation

We account for stock-based compensation awards in accordance with FASB ASC Topic 718, Compensation—Stock Compensation (ASC 718). ASC 718 requires all stock-based payments including grants of stock options and restricted stock and modifications to existing stock options, to be recognized in the consolidated statements of operations based on their fair values.

Our stock-based awards are subject to either service-based or performance-based vesting conditions. Vesting of certain awards could also be accelerated upon achievement of defined market-based vesting conditions. We also have issued several stock options with exercise prices denominated in a foreign currency that are required to be accounted for as liabilities. We account for employee stock-based awards at grant-date fair value. We account for non-employee and liability-classified stock-based awards based on the then-current fair values at each financial reporting date until the performance is complete for non-employee awards, or until the award is settled (exercised) for liability-classified awards. Changes in the amounts attributed to these awards between the reporting dates are included in stock-based compensation expense (credit) in our statements of operations. We include liability-classified stock options into non-current liabilities in our balance sheets as their settlement (exercise) does not require use of cash, cash equivalents or other current assets.

We record compensation expense for service-based awards over the vesting period of the award on a straight-line basis. Compensation expense related to awards with performance-based vesting conditions is recognized over the requisite service period using the accelerated attribution method to the extent achievement of the performance condition is probable. Compensation expense for awards with service- and market-based vesting conditions is recognized using the accelerated attribution method over the shorter of the requisite service period or the implied period associated with achievement of the market-based vesting provisions.

We estimate the fair value of our option awards using the Black-Scholes option pricing model, which requires the input of subjective assumptions, including (i) the expected stock price volatility, (ii) the expected term of the award, (iii) the risk-free interest rate and (iv) expected dividends. Due to the lack of historical and implied volatility data of our common stock, we based our estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded. We selected companies with comparable characteristics to us, including enterprise value, risk profiles and position within the industry, and with historical share price information sufficient to meet the expected term of the stock-based awards. We compute historical volatility data using the daily closing prices for the selected companies' shares during the equivalent period of the calculated expected term of the stock-based awards.

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We have estimated the expected term of employee service-based stock options using the “simplified” method, whereby the expected term equals the arithmetic average of the vesting term and the original contractual term of the option, due to our lack of sufficient historical data. We have estimated the expected term of employee awards with service and market conditions using a Monte-Carlo simulation model. This approach involves generating random stock-price paths through a lattice-type structure. Each path results in a certain financial outcome, such as accelerated vesting or specific option payout. We have estimated the expected term of nonemployee service- and performance-based awards based on the remaining contractual term of such awards.

The risk-free interest rates for periods within the expected term of the option are based on the Swedish Government Bond rate with a maturity date commensurate with the expected term of the associated award. We have never paid dividends, and do not expect to pay dividends in the foreseeable future.

We are also required to estimate forfeitures at the time of grant, and revise those estimates in subsequent periods if actual forfeitures differ from estimates. We record stock-based compensation expense only for those awards that are expected to vest. To the extent that actual forfeitures differ from our estimates, the differences are recorded as a cumulative adjustment in the period the estimates were revised. Historical forfeitures have been insignificant.

Income taxes

We use the asset and liability method of accounting for income taxes in accordance with ASC Topic 740, Income Taxes. Under this method, income tax expense is recognized for the amount of (1) taxes payable or refundable for the current year and (2) deferred tax consequences of temporary differences resulting from matters that have been recognized in an entity’s financial statements or tax returns.

Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in the results of operations in the period that includes the enactment date. A valuation allowance is provided to reduce the deferred tax assets reported if, based on the weight of the available positive and negative evidence, it is more likely than not some portion or all of the deferred tax assets will not be realized.

ASC Topic 740.10.30 clarifies the accounting for uncertainty in income taxes recognized in an enterprise’s financial statements and prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. ASC Topic 740.10.40 provides guidance on de-recognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. We have no material uncertain tax positions for any of the reporting periods presented.

We recognize interest and penalties related to uncertain tax positions in income tax expense. As of December 31, 2013 and 2014, we had no accrued interest or penalties related to uncertain tax positions and no amounts have been recognized in our statements of operations.

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U.S. government grants

In 2013 and 2014, we recognized \$0.2 million and \$0, respectively, from the U.S. federal government Small Business Innovation Research/Small Business Technology Transfer grants to support our research and development activities as a reduction to our research and development expenses.

Net loss per share

Basic net loss per share is calculated by dividing the net loss attributable to common stockholders by the weighted average number of shares of common stock outstanding during the period. Diluted net loss per share is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of common equivalent stock outstanding for the period, including any dilutive effect from outstanding stock options. Shares used in the diluted net loss per share calculations exclude anti-dilutive common equivalent shares, which consist of stock options. These anti-dilutive shares of common stock totaled 465,540 shares and 925,077 shares for the years ended December 31, 2013 and 2014, respectively. While these common equivalent shares are currently anti-dilutive, they could be dilutive in the future.

Subsequent events

We consider events or transactions that occur after the balance sheet date, but prior to the issuance of the financial statements, to provide additional evidence relative to certain estimates or to identify matters that require additional disclosure.

Recently adopted accounting pronouncements

During the quarter ended September 30, 2014, the FASB issued ASU No. 2014-15, Presentation of Financial Statements—Going Concern (ASU No. 2014-15). The new guidance addresses management's responsibility to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern and to provide related footnote disclosures. Management's evaluation should be based on relevant conditions and events that are known and reasonably knowable at the date that the financial statements are issued. The standard will be effective for the first interim period within annual reporting periods beginning after December 15, 2016. Early adoption is permitted, but we have not elected to do so. We do not expect the adoption of ASU 2014-15 to have an impact on our financial position or results of operations.

3. Fair value measurement

The following table sets forth the fair value of our financial assets by level within the fair value hierarchy. Our foreign currency forward contracts are classified within Level II because of the use of observable inputs for similar derivative instruments in active markets, or quoted prices for identical or

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similar instruments in markets that are not active, and are directly or indirectly observable, and are classified as prepaid expenses and other current assets (in thousands):

	As of December 31, 2013			
	Level I	Level II	Level III	Total
Financial assets:				
Foreign currency forward contracts	\$—	\$159	\$—	\$159
Total financial assets	\$—	\$159	\$—	\$159

	As of December 31, 2014			
	Level I	Level II	Level III	Total
Financial assets:				
Foreign currency forward contracts	\$—	\$438	\$—	\$438
Total financial assets	\$—	\$438	\$—	\$438

4. In-process research and development and goodwill

The gross carrying amount of in-process research and development and goodwill is as follows (in thousands):

	As of December 31, 2013			
	Cost	Additions	Disposals	Total
In-process research and development	\$5,228	\$—	\$—	\$5,228
Goodwill	2,200	—	—	2,200
Total	\$7,428	\$—	\$—	\$7,428

	As of December 31, 2014			
	Cost	Additions	Disposals	Total
In-process research and development	\$5,228	\$—	\$—	\$5,228
Goodwill	2,200	—	—	2,200
Total	\$7,428	\$—	\$—	\$7,428

Goodwill and in-process research and development as of December 31, 2013 and 2014 resulted from our acquisition of BioPancreate. In-process research and development is initially measured at its fair value and is not amortized until commercialization. Once commercialization occurs, in-process research and development will be amortized over its estimated useful life. We did not identify any indicators of impairment of our in-process research and development as of December 31, 2014.

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5. Accrued liabilities

Accrued liabilities consist of the following (in thousands):

	<u>As of December 31,</u>	
	<u>2013</u>	<u>2014</u>
Consulting and professional fees	\$366	\$ 516
Employee compensation	391	804
Other	70	102
Total accrued liabilities	<u>\$827</u>	<u>\$1,422</u>

6. Commitments and contingencies

(a) Lease

On April 22, 2014, we entered into a 48-month building lease for approximately 3,000 square feet of space in Radnor, Pennsylvania. The lease has annual rent escalations. We obtained access to the newly leased space on August 1, 2014, and this was considered the lease commencement date for accounting purposes. Thus, rent expense began on this date and is recognized on a straight-line basis over the term of the lease.

As of December 31, 2014, future minimum commitments under facility operating leases were as follows (in thousands):

	<u>Operating leases</u>
2015	\$111
2016	114
2017	118
2018	<u>121</u>
Total minimum lease payments	<u>\$464</u>

Rent expense recognized under our operating lease, including additional rent charges for utilities, parking, maintenance and real estate taxes, was \$52,000 and \$83,000 for the years ended December 31, 2013 and 2014, respectively.

The above table excludes the impact of entering into the sublease for our Trevoze, Pennsylvania facility in March 2015. We entered into a 52-month building sublease agreement for 14,743 square feet of office space with annual rent escalations. Minimum commitments under the sublease agreement are approximately \$236,000, \$193,000, \$274,000, \$297,000 and \$184,000 during 2015, 2016, 2017, 2018 and 2019, respectively. Additionally, during the second quarter of 2015, we vacated the Radnor facility and commenced efforts to sublease the facility. We have not yet determined the accounting impact of vacating the Radnor facility.

(b) License Agreement

On March 30, 2011, a license agreement was executed between BioPancreate and the Cornell Center for Technology Enterprise and Commercialization (CCTEC). Under the terms of the license

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agreement, BioPancreate obtained certain rights from the CCTEC for commercial development, use and sale of products that use the technology associated with the license.

License issue fees payable to the CCTEC include \$15,000 paid within 30 days after the execution of the agreement (Effective Date) and \$235,000 to be paid in five equal installments of \$47,000 payable annually within 30 day of the Effective Date's respective anniversary. As of December 31, 2014, there were two remaining installments to be paid. We are obligated to make milestone payments upon the achievement of certain regulatory and clinical milestones up to \$2.6 million in the aggregate. For years in which licensed products are sold, we are required to pay a royalty based on a low single-digit percentage of net sales. The minimum annual royalty in such years is \$100,000.

In the event the product is sublicensed, up to \$3.5 million of certain fees we receive that are not earned royalties or reimbursements for direct costs are due to the CCTEC upon achievement of certain regulatory and clinical milestones.

(c) Other Commitments

In 2012, we entered into consulting agreements with two individuals to serve as Chief Executive Officer and Chief Operating Officer, respectively. In connection with those agreements, each individual is entitled to a payment in the event of the sale or license by us prior to December 31, 2016 of BioPancreate or major assets derived from the BioPancreate technology. The payment amounts are based on a percentage of the acquisition price or up-front license fee, as applicable. The maximum amount payable per individual in the event of a sale or license is \$2.5 million or \$1.25 million, respectively. Each individual is entitled to such payments even though each is no longer serving in their respective officer roles.

7. Business combinations

On December 20, 2012, we increased our equity interest in BioPancreate from 20% to 49% by issuing 554,772 shares of our common stock. In addition, as part of the transaction there was an option to exchange the remaining shares of BioPancreate for 341,408 shares of our common stock that could be exercised by us or the holders of the BioPancreate shares. The option was to expire on September 1, 2016 and was contingent on certain conditions, including our commitment to fund the BioPancreate development plan in excess of any grants BioPancreate could be awarded until BioPancreate obtained U.S. Investigational New Drug approval.

We accounted for the 2012 increase in our equity ownership of BioPancreate using the acquisition method of accounting for business combinations because we concluded that BioPancreate was a variable interest entity and we were the primary beneficiary of BioPancreate. We determined that BioPancreate was a variable interest entity because it did not have sufficient equity to finance its research and development activities. In evaluating whether we were the primary beneficiary, we considered our ability and commitment to fund BioPancreate's development plans and our option to acquire the remaining shares of BioPancreate. These conditions resulted in our power to direct BioPancreate's activities that most significantly impacted its economic performance, specifically research and development activities, and our obligation or right to absorb the losses or benefit from the research and development activities of BioPancreate.

The consideration of the 554,772 shares to increase our equity ownership interest from 20% to 49% of BioPancreate was based on the fair value of our common stock on the date of the acquisition.

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The fair value of our common stock of \$4.86 per share was based on our management's valuation as of December 20, 2012, using the risk-adjusted cash flow method. As a result of the transaction, we recorded \$2.2 million of goodwill and \$5.2 million of in-process research and development. The remaining 51% was recorded as non-controlling interests with a fair value of \$1.7 million. BioPancreate had a stock option plan that remained outstanding after the acquisition. The fair value of the vested stock options under the plan was recorded as part of non-controlling interest as of the acquisition date.

On October 29, 2013, we exercised our option to acquire the remaining interest in BioPancreate. As consideration for this acquisition of shares, we issued 336,136 shares of our common stock in October 2013 and an additional 5,272 shares of our common stock in January 2014. The transaction was recorded as an equity transaction and the previously held non-controlling interest in BioPancreate was reclassified to equity.

As part of the transaction, we also replaced BioPancreate's stock options with our stock options. This transaction was recorded as a modification. Accordingly, the excess in fair value of approximately \$54,000 was recorded as compensation expense for the year ended December 31, 2013.

8. Income taxes

For the years ended December 31, 2013 and 2014, the components of loss before income taxes were as follows (in thousands):

	Year Ended December 31,	
	2013	2014
Sweden	\$(5,267)	\$ (9,165)
U.S.	(213)	(985)
Total	<u>\$(5,480)</u>	<u>\$(10,150)</u>

The components of income tax (benefit) for the years ended December 31, 2013 and 2014 were as follows (in thousands):

	Year Ended December 31,	
	2013	2014
Current tax expense (benefit):		
Sweden	\$ —	\$ —
U.S.		
Federal	—	—
State	—	—
Total	<u>\$ —</u>	<u>\$ —</u>
Deferred tax expense (benefit):		
Sweden	\$ (761)	\$ (648)
U.S.		
Federal	(903)	(2,433)
State	(225)	(720)
Change in valuation allowance	1,796	3,321
Total	<u>\$ (93)</u>	<u>\$ (480)</u>

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We recorded tax benefits for the federal and state net operating loss carry forwards and federal tax credit carryforwards attributable to BioPancreate. These deferred benefits are realizable as they offset the non-current deferred tax liability recorded in connection with the acquisition of BioPancreate.

We have incurred net operating losses since inception. We have not reflected any benefit of net operating loss carryforwards (NOLs), other than those attributable to BioPancreate, in the accompanying financial statements. We have established a valuation allowance against the remaining deferred tax assets due to the uncertainty surrounding the realization of such assets.

Deferred taxes are recognized for temporary differences between the bases of assets and liabilities for financial statement and income tax purposes. The tax effect of temporary differences that give rise to significant portions of the deferred tax assets are as follows (in thousands):

	Year Ended December 31,	
	2013	2014
Deferred tax assets:		
Net operating loss carryforwards	\$ 7,096	\$ 8,775
Tax credits	1,689	3,811
Capitalized research and development costs	161	161
Total deferred tax assets	8,946	12,747
Valuation allowance	(8,691)	(12,012)
Deferred tax assets recognized	255	735
Deferred tax liabilities:		
Acquired intangible assets	(2,111)	(2,111)
Total deferred tax liabilities	(2,111)	(2,111)
Net deferred tax liabilities	\$(1,856)	\$ (1,376)

We have evaluated the positive and negative evidence bearing upon the realizability of our deferred tax assets. Based on our history of operating losses, we have concluded that it is more likely than not that the benefit of our deferred tax assets, other than those attributable to BioPancreate, will not be realized. Accordingly, we have provided a full valuation allowance for the remaining deferred tax assets as of December 31, 2013 and 2014. The valuation allowance increased by approximately \$1.8 million and \$3.3 million during the year ended December 31, 2013 and 2014, respectively, due primarily to net operating losses.

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The effective tax rate of our benefit for income taxes differs from the statutory rate as follows:

	<u>Year Ended</u> <u>December 31,</u>	
	<u>2013</u>	<u>2014</u>
Swedish statutory income tax rate	22.0%	22.0%
Income tax differential between U.S. and Sweden	0.7	1.8
Elimination of double-count of losses deductible in both Sweden and U.S.	(8.2)	(13.5)
Federal tax credits	15.2	20.9
Net operating loss carryforwards for Strongbridge and BioPancreate . . .	4.1	7.1
Change in valuation allowance	(32.8)	(32.7)
Other	0.7	(0.9)
Effective income tax rate	<u>1.7%</u>	<u>4.7%</u>

At December 31, 2014, we had approximately \$43.5 million of Swedish NOLs, which have an indefinite life, and approximately \$1.1 million of U.S. federal and \$12.0 million of state NOLs, which begin to expire in 2031. We operate through a permanent establishment in the United States. Income from the permanent establishment is taxed in both Sweden and the United States. Relief is granted by way of crediting the U.S. tax against the Swedish tax. This tax credit can never exceed the Swedish tax on the income. Since the tax rate is higher in the United States than in Sweden, the Swedish taxable carryforward losses of \$43.5 million can only generate a tax benefit if income is derived from sources other than the permanent establishment in the United States.

At December 31, 2014, we had \$3.7 million of U.S. federal orphan drug tax credit carryforwards, which begin to expire in 2032, and \$107,000 of U.S. federal research and development tax credit carryforwards, which begin to expire in 2031.

Utilization of the NOLs may be subject to limitations under Swedish tax regulations or U.S. Internal Revenue Code Section 382 if there is a greater than 50% ownership change as determined under applicable regulations.

9. Ordinary shares

Voting rights and privileges

The holders of shares of our common stock are entitled to one vote for each ordinary share held at all meetings of stockholders without limitation and written actions in lieu of meetings. The holders are entitled to receive dividends if and when declared by our Board of Directors. No dividends have been declared or paid since our inception. The holders are entitled to share ratably in our assets available for distribution to stockholders, in the event of any voluntary or involuntary liquidation.

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Equity financings

In May 2013, we executed subscription agreements with two investors to issue 146,909 shares of common stock for \$653,000, net of transaction costs. Under the subscription agreements, we had the right to issue additional shares (put options) to the investors at a specified price per share based on our successful achievement of certain milestones. In June 2013, we satisfied the first milestone, which was Investigational New Drug approval by the U.S. Food and Drug Administration (FDA) for our COR-003 product candidate. Upon satisfaction of the milestone, we issued 400,661 shares of common stock to the two investors for \$2.0 million, net of transaction costs. The milestone for the third tranche was not satisfied timely in accordance with the terms of the agreement and, therefore, no further shares were issued pursuant to the subscription agreements.

We concluded that although the put options were freestanding instruments, the first put option was only outstanding for a short period of time, from May to June 2013, and with a general expectation that the FDA approval would be received. Because of these conditions, the value of the expected approval was reflected in the value of the common stock in the initial issuance. Therefore, the impact of any remeasurement of these put options would have been immaterial. Regarding the second put option associated with the third tranche of shares, we concluded that it was not probable that the related milestone would be achieved and therefore assigned no value to it.

In September 2013, we issued 1,842,751 shares of common stock for \$12.0 million, net of transaction costs.

In December 2014, we issued 1,755,909 shares of common stock for \$10.2 million, net of transaction costs.

Shares reserved for issuance

There were 465,540 and 925,077 shares of common stock reserved for future issuance upon exercise of stock options as of December 31, 2013 and 2014, respectively.

10. Stock-based compensation

Our Board of Directors and our shareholders approve the granting of stock options to our officers, directors, other key employees and third party-consultants. Under these grants, the beneficiaries are given the right to acquire new shares of common stock at a pre-determined option price. The purpose of the grants is to assist us in attracting, retaining and motivating officers, employees, directors and consultants. In addition, these awards provide us with the ability to provide incentives that are directly linked to the performance of our business and the related increase in shareholder value.

Stock options grants have a maximum term of five years. As determined by our Board of Directors, our stock-based awards vest over periods ranging up to four years or upon achievement of defined performance criteria. In addition, vesting of certain awards could be accelerated when the fair value of our stock reaches defined targets.

The exercise price for each stock option is determined by the Board of Directors based upon considerations such as the fair value of the underlying common stock and certain market conditions. The determination of the fair value of our common stock takes into account the price at which our shares are being traded on the NOTC, recent equity financings and third-party valuations.

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A summary of the outstanding stock options as of December 31, 2014 is as follows:

	Options Outstanding			
	Number of Shares	Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in thousands)
Outstanding—January 1, 2013	272,727	\$ 2.81	4.33	\$ 584
Granted	192,813	\$ 7.21		
Exercised	—			
Outstanding—December 31, 2013	465,540	\$ 4.63	3.76	\$1,182
Granted	504,990	\$11.18		
Forfeited	(45,453)	\$ 8.64		
Exercised	—			
Outstanding—December 31, 2014	<u>925,077</u>	\$ 8.01	3.72	\$1,011
Vested and exercisable—December 31, 2014	<u>470,991</u>	\$ 4.39	2.74	\$1,004
Vested and expected to vest—December 31, 2014	<u>925,077</u>	\$ 8.01	3.72	\$1,011

Included in the options outstanding at December 31, 2014 are stock options to purchase 299,999 shares at a weighted average exercise price of \$3.01 per share accounted for as liabilities, which were fully vested as of December 31, 2014, and stock options to purchase 436,360 shares at a weighted average exercise price of \$11.88 per share which are subject to acceleration if the fair value per share of our stock reaches 132 Norwegian Kroner (\$17.71 at December 31, 2014), which were all unvested as of December 31, 2014.

The aggregate intrinsic values of options outstanding, vested and exercisable, and vested and expected to vest were calculated as the difference between the exercise price of the options and the estimated fair value of our common stock as of January 1, 2013, December 31, 2013 and December 31, 2014, respectively.

Stock-based compensation expense

We recognized stock-based compensation expense for employees and non-employees in the accompanying consolidated statements of operations as follows (in thousands):

	Year Ended December 31,	
	2013	2014
Research and development	\$438	\$268
General and administrative	310	(17)
Total stock-based compensation	<u>\$748</u>	<u>\$251</u>

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Included in these amounts was stock compensation expense (credit) attributed to liability-classified awards of \$402,000 and \$(229,000), for the years ended December 31, 2013 and 2014, respectively. As of December 31, 2014, the total unrecognized compensation expense related to unvested options, net of estimated forfeitures, was \$0.6 million, which we expect to recognize over an estimated weighted-average period of 1.75 years.

In determining the estimated fair value of the stock-based awards, we use the Black-Scholes option-pricing model and assumptions discussed below. Each of these inputs is subjective and generally requires significant judgment to determine.

The fair value of stock option awards was estimated with the following assumptions:

	Year Ended December 31,	
	2013	2014
Expected term (in years)	4.42	3.23
Risk-free interest rate	1.1%-1.7%	0.0%-0.6%
Expected volatility	70.8%-84.4%	68.3%-80.7%
Dividend rate	0%	0%

11. Subsequent events

On January 12, 2015, we entered into a share purchase agreement with investors whereby we would issue, subject to stockholder approval, 4,761,078 shares of our common stock for \$25.8 million, net of transaction costs. Stockholder approval was obtained and the financing was completed on February 18, 2015.

Under the terms of the share purchase agreement, we agreed to use all reasonable efforts to complete an IPO within the United States within ten months from the issuance date of the our common stock that was issued to these investing shareholders. If completing a U.S. IPO was not feasible, we agreed to complete an IPO on the Norwegian Stock Exchange (NSE) within ten months from the issuance date of common stock to these investing shareholders.

On May 13, 2015, we entered into an exclusive license agreement with Antisense Therapeutics Limited, or Antisense Therapeutics, that provides us with development and commercialization rights to Antisense Therapeutics' product candidate, ATL1103, for endocrinology applications. We refer to this product candidate as COR-004. Under the terms of the agreement, we provided Antisense Therapeutics with an initial upfront license payment of \$3.0 million in cash, and we also invested \$2.0 million in Antisense Therapeutics equity. We may become obligated to make additional payments, contingent upon achieving specific development and commercialization milestones, of up to \$105.0 million over the lifetime of the agreement. We may also be required to make royalty payments based on a percentage, ranging from the mid-single digits to the mid-teens, of net sales of COR-004 during the period that we are selling COR-004, if approved. We will be responsible for the future clinical development of COR-004 in endocrinology applications and for the funding of associated future development, regulatory and drug manufacture costs. Antisense Therapeutics will retain commercialization rights for COR-004 in endocrinology applications in Australia and New Zealand as well as worldwide rights for COR-004 in indications other than endocrinology, and may utilize any new COR-004 data generated by us in pursuing these other indications, subject to specified terms and conditions set forth in our license agreement.

CORTENDO AB
(Predecessor of STRONGBRIDGE BIOPHARMA plc)
Notes to Consolidated Financial Statements (Continued)

On June 29 and 30, 2015, following shareholder approval of the share purchase agreement into which we entered on May 14, 2015, we raised \$32.6 million, net of transaction costs, in a private placement, the proceeds of which will be used primarily for the continued development of COR-003, along with the planned development of our two new programs, COR-004 and COR-005, and for general corporate purposes. The subscription price was \$14.54 per share and 2,284,414 new shares were issued to the investors.

On June 30, 2015, following shareholder approval of the agreement into which we entered on May 14, 2015, we acquired from Aspireo Pharmaceuticals Ltd., an Israeli company, its product candidate, DG3173. We refer to this product candidate as COR-005. Under the terms of the acquisition agreement, we issued to Aspireo Pharmaceuticals \$30.0 million in Cortendo equity at \$14.54 per common share, or 2,062,677 common shares, in exchange for COR-005. In connection with this acquisition, we made a payment to the Office of the Chief Scientist of the Israeli Ministry of Economy, or OCS, in the amount of \$3.0 million, which represents the repayment of amounts granted by the OCS to Aspireo Pharmaceuticals, plus interest, that were used in support of research and development conducted by Aspireo Pharmaceuticals for the development of DG3173. In accordance with ASC 805, we have determined that the transaction will be accounted for as a business combination.

CORTENDO AB
(Predecessor of STRONGBRIDGE BIOPHARMA plc)
Interim Consolidated Balance Sheets
(In thousands, except share and per share data)

	<u>December 31,</u> <u>2014</u>	<u>June 30, 2015</u> <u>(unaudited)</u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 15,632	\$ 54,387
Prepaid expenses and other current assets	598	1,351
Total current assets	16,230	55,738
Property and equipment, net	21	40
In-process research and development	5,228	36,551
Goodwill	2,200	7,256
Other assets	10	1,327
Total assets	\$ 23,689	\$100,912
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 887	\$ 5,395
Accrued liabilities	1,422	3,503
Total current liabilities	2,309	8,898
Stock-based liability awards	1,183	3,529
Deferred tax liabilities	1,376	1,199
Total liabilities	4,868	13,626
Commitments and contingencies (Note 7)		
Stockholders' equity:		
Common stock, \$0.01 par value, 175,000,000 and 600,000,000 shares authorized at December 31, 2014 and June 30, 2015; 9,700,789 and 18,808,958 shares issued and outstanding at December 31, 2014 and June 30, 2015	97	188
Additional paid-in capital	55,947	147,838
Accumulated deficit	(37,223)	(60,740)
Total stockholders' equity	18,821	87,286
Total liabilities and stockholders' equity	\$ 23,689	\$100,912

The accompanying notes are an integral part of these interim consolidated financial statements.

CORTENDO AB
(Predecessor of STRONGBRIDGE BIOPHARMA plc)
Interim Consolidated Statements of Operations
(In thousands, except share and per share data)
(unaudited)

	<u>Six Months Ended June 30,</u>	
	<u>2014</u>	<u>2015</u>
Operating expenses:		
Research and development	\$ 2,460	\$ 10,218
General and administrative	1,298	12,620
Total operating expenses	<u>3,758</u>	<u>22,838</u>
Operating loss	(3,758)	(22,838)
Other income (expense), net:		
Foreign exchange gain (loss)	165	(314)
Other income (expense), net	166	(543)
Total other income (expense), net	<u>331</u>	<u>(857)</u>
Loss before income taxes	(3,427)	(23,695)
Income tax benefit	225	178
Net loss	<u>\$ (3,202)</u>	<u>\$ (23,517)</u>
Net loss attributable to ordinary shareholders:		
Basic and diluted	<u>\$ (3,202)</u>	<u>\$ (23,517)</u>
Net loss per share attributable to ordinary shareholders:		
Basic and diluted	<u>\$ (0.40)</u>	<u>\$ (1.75)</u>
Weighted-average shares used in computing net loss per share attributable to ordinary shareholders:		
Basic and diluted	<u>7,939,608</u>	<u>13,433,712</u>

The accompanying notes are an integral part of these interim consolidated financial statements.

CORTENDO AB
(Predecessor of STRONGBRIDGE BIOPHARMA plc)
Interim Consolidated Statements of Shareholders' Equity
(In thousands except share amounts)
(unaudited)

	<u>Ordinary Shares</u>	<u>Ordinary Shares Amount</u>	<u>Additional Paid-In Capital</u>	<u>Accumulated Deficit</u>	<u>Total Shareholders' Equity</u>
Balance—December 31, 2014	9,700,789	\$ 97	\$ 55,947	\$(37,223)	\$ 18,821
Net loss	—	—	—	(23,517)	(23,517)
Stock-based compensation	—	—	473	—	473
Issuance of shares	9,108,169	91	91,418	—	91,509
Balance—June 30, 2015	<u>18,808,958</u>	<u>\$188</u>	<u>\$147,838</u>	<u>\$(60,740)</u>	<u>\$ 87,286</u>

The accompanying notes are an integral part of these interim consolidated financial statements.

CORTENDO AB
(Predecessor of STRONGBRIDGE BIOPHARMA plc)
Interim Consolidated Statements of Cash Flow
(In thousands)
(unaudited)

	Six Months Ended June 30,	
	2014	2015
Cash flows from operating activities:		
Net loss	\$(3,202)	\$(23,517)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2	6
Stock-based compensation	146	2,819
Deferred income tax benefit	(225)	(177)
Foreign exchange loss	10	209
Change in fair value of foreign currency forward contracts	(33)	438
Changes in operating assets and liabilities, net of effect of acquisition:		
Accounts payable and accrued liabilities	(249)	7,065
Prepaid expenses and other current assets	(173)	(2,508)
Net cash used in operating activities	<u>(3,724)</u>	<u>(15,665)</u>
Cash flows from investing activities:		
Payments for acquisitions	—	(3,168)
Purchase of equipment	(5)	(25)
Net cash used in investing activities	<u>(5)</u>	<u>(3,193)</u>
Cash flows from financing activities:		
Proceeds from issuance of ordinary shares	—	58,298
Net cash provided by financing activities	<u>—</u>	<u>58,298</u>
Effect of exchange rate changes on cash and cash equivalents	(10)	(685)
Net increase (decrease) in cash and cash equivalents	(3,739)	38,755
Cash and cash equivalents—beginning of period	14,897	15,632
Cash and cash equivalents—end of period	<u>\$11,158</u>	<u>\$ 54,387</u>
Supplemental non-cash investing and financing activities:		
Ordinary shares issued for acquisition of COR-005	\$ —	\$ 33,211
Acquisition of in-process research and development	<u>\$ —</u>	<u>\$(31,323)</u>

The accompanying notes are an integral part of these interim consolidated financial statements.

CORTENDO AB
(Predecessor of STRONGBRIDGE BIOPHARMA plc)
Notes to Interim Consolidated Financial Statements (Unaudited)

1. Organization

Cortendo AB is a biopharmaceutical company incorporated in Sweden and based in the United States. We are focused on the development, in-licensing, acquisition and eventual commercialization of multiple complementary products and product candidates within the franchises that target rare diseases. Our primary focus to date has been to build our rare endocrine franchise, which includes product candidates for the treatment of Cushing's syndrome and acromegaly, two rare diseases with a high unmet need for innovative treatment options. We also intend to identify and in-license or acquire products or product candidates that will be complementary to our existing rare endocrine franchise or that would form the basis for new rare disease franchises.

Our shares are currently quoted on the Norwegian Over-The-Counter Market, or NOTC,-A list.

Exchange offer

On May 26, 2015, Strongbridge Biopharma plc (then named Cortendo plc), was incorporated under the laws of Ireland.

On August 7, 2015, Strongbridge Biopharma plc initiated an exchange offer for the outstanding shares of Cortendo AB. The exchange offer was structured as a one-for-one exchange offer in which shareholders of Cortendo AB exchanged their common shares, with a par value of \$0.15, for beneficial interests in ordinary shares of Strongbridge Biopharma plc, with a par value of \$0.01, in the form of Norwegian depositary receipts and, as the case may be, Swedish depositary receipts (except for non-accredited investors who hold Cortendo AB shares located in the United States, who were offered cash in an amount equivalent to the value of the Strongbridge Biopharma plc shares such investors would otherwise receive for their Cortendo AB shares exchanged).

The exchange offer was settled on September 8, 2015, and Cortendo AB became a subsidiary with 99.582% of its shares being owned by Strongbridge Biopharma plc. Accordingly, Strongbridge Biopharma plc is a continuation of Cortendo AB, the predecessor, and the consolidated financial statements represent the assets, liabilities and results of operations of Cortendo AB, for all periods presented.

On September 8, 2015, Strongbridge Biopharma plc effected a 1-for-11 reverse stock split of its ordinary shares. Accordingly, the interim consolidated financial statements and notes retroactively reflect the capital structure of Strongbridge Biopharma plc after giving effect to the exchange offer and the reverse stock split. With affect from September 8, 2015, the 0.418% of Cortendo AB not owned by Strongbridge Biopharma plc, will be accounted for as a non-controlling interest.

Liquidity

We believe that our cash resources of \$54.4 million at June 30, 2015, will be sufficient to allow us to fund our current operating plan for at least the next 12 months. As we continue to incur losses, our transition to profitability is dependent upon the successful development, approval and commercialization of our product candidates and achieving a level of revenues adequate to support our cost structure. We may never achieve profitability, and unless and until we do, we will continue to need to raise additional capital. Our management intends to fund future operations through additional equity offerings, and may seek additional capital through issuance of debt, arrangements with strategic partners or from other sources. There can be no assurances, however, that additional funding will be available on terms acceptable to us.

CORTENDO AB
(Predecessor of STRONGBRIDGE BIOPHARMA plc)

Notes to Interim Consolidated Financial Statements (Unaudited) (Continued)

2. Summary of significant accounting policies and basis of presentation

Basis of presentation and principles of consolidation

The accompanying interim consolidated financial statements include the accounts of our wholly owned subsidiaries, BioPancreate Inc. (Trevose, Pennsylvania, United States), Cortendo Invest AB (Gothenburg, Sweden) and Cortendo Caymans (Georgetown, Cayman Islands). All intercompany balances and transactions have been eliminated in consolidation. These unaudited interim consolidated financial statements have been prepared in conformity with generally accepted accounting principles in the United States (U.S. GAAP) for interim financial information. Any reference in these notes to applicable guidance is meant to refer to the authoritative U.S. GAAP as found in the Accounting Standards Codification (ASC) and Accounting Standards Update (ASU) of the Financial Accounting Standards Board (FASB). In the opinion of management, the accompanying financial statements include all normal and recurring adjustments (which consist primarily of accruals, estimates and assumptions that impact the financial statements) considered necessary to present fairly the Company's financial position as of June 30, 2015 and its results of operations and cash flows for the six months ended June 30, 2014 and 2015. Operating results for the six months ended June 30, 2015 are not necessarily indicative of the results that may be expected for the year ending December 31, 2015. The interim financial statements presented herein do not contain the required disclosures under U.S. GAAP for annual financial statements.

Foreign currency translation

The interim consolidated financial statements are reported in United States dollars, which is the functional currency of our subsidiaries and Cortendo AB. Transactions in foreign currencies are translated into our functional currency at the rate of exchange prevailing at the date of the transaction. Any monetary assets and liabilities arising from these transactions are translated into our functional currency at exchange rates prevailing at the balance sheet date or on settlement. Resulting gains and losses are recorded in foreign exchange loss in our consolidated statements of operations.

Use of estimates

The preparation of the interim financial statements in conformity with U.S. GAAP requires us to make estimates and assumptions that affect the reported amounts in the financial statements and accompanying notes. We must apply significant judgment in this process. Actual results could materially differ from those estimates.

Segment information

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker, or decision making group, in making decisions on how to allocate resources and assess performance. We view our operations and manage our business in one operating segment. Our material long-lived assets, which consist of in-process research and development, reside in the United States.

Cash and cash equivalents

We consider all short-term highly liquid investments with an original maturity at the date of purchase of three months or less to be cash equivalents. Cash and cash equivalents consist of account balances at banks and money market accounts, respectively.

CORTENDO AB
(Predecessor of STRONGBRIDGE BIOPHARMA plc)

Notes to Interim Consolidated Financial Statements (Unaudited) (Continued)

Concentration of credit risk and other risks and uncertainties

Cash deposits in Sweden and Norway as of December 31, 2014 and June 30, 2015 of \$15.4 million and \$6.9 million, respectively, are subject to local banking laws and may bear higher or lower risk than cash deposited in the United States. As part of our cash and investment management processes, we perform periodic evaluations of the credit standing of the financial institutions with which we deposit our cash or purchase cash equivalents, and we have not sustained any credit losses from instruments held at these financial institutions.

We are exposed to concentrations of credit risk through the foreign currency forward contracts into which we enter to the extent we have recorded an asset in relation thereto. The counterparties to the agreements relating to our foreign currency forward contracts consist of financial institutions with high credit standing and accordingly we do not believe there is significant risk related to non-performance by these counterparties due to credit risk.

Fair value of financial instruments

Fair value accounting is applied for all financial assets and liabilities and non-financial assets and liabilities that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually).

We are required to disclose information on all assets and liabilities reported at fair value that enables an assessment of the inputs used in determining the reported fair values. FASB ASC Topic 820, Fair Value Measurements and Disclosures (ASC 820), establishes a hierarchy of inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the observable inputs be used when available. Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of us. Unobservable inputs are inputs that reflect our assumptions about the inputs that market participants would use in pricing the asset or liability, and are developed based on the best information available in the circumstances. The fair value hierarchy applies only to the valuation inputs used in determining the reported fair value of the investments and is not a measure of the investment credit quality. The three levels of the fair value hierarchy are described as follows:

Level 1—Valuations based on unadjusted quoted prices in active markets for identical assets or liabilities that we have the ability to access at the measurement date.

Level 2—Valuations based on quoted prices for similar assets or liabilities, or quoted prices in markets that are not active, and for which all significant inputs are observable, either directly or indirectly.

Level 3—Valuations that require inputs that reflect our own assumptions that are both significant to the fair value measurement and unobservable. To the extent that valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment we exercise in determining fair value is greatest for instruments categorized in Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

We entered into foreign currency forward contracts to offset some of the foreign exchange risks we bear on operating expenses that are not denominated in U.S. dollars. These instruments are not

CORTENDO AB
(Predecessor of STRONGBRIDGE BIOPHARMA plc)

Notes to Interim Consolidated Financial Statements (Unaudited) (Continued)

entered into for speculative purposes and, although we believe they serve as effective economic hedges, we do not seek to qualify for hedge accounting.

These forward contracts are recorded at fair value on the accompanying interim consolidated balance sheets as prepaid expenses and other current assets. These forward contracts are measured using observable quoted prices for similar instruments. The outstanding notional amount of our unsettled foreign currency forward contracts as of December 31, 2014 and June 30, 2015 was \$2.3 million and \$0, respectively, and the fair values of those assets were \$438,000 and \$0, respectively. The forward contracts were settled during the period ended June 30, 2015. The gain and loss recognized in other income, net, for these forward contracts was \$33,000 and \$(438,000) for the six months ended June 30, 2014 and 2015, respectively. These amounts represent the net gain or loss on the forward contracts and do not include changes in the related exposures, which generally offset a portion of the gain or loss on the forward contracts.

Counterparties to these instruments are major financial institutions with credit ratings of investment grade or better and no collateral is required. We believe the risk of incurring any losses on these forward contracts related to credit risk is remote.

On May 13, 2015, as part of our agreement to acquire an exclusive license agreement from Antisense Therapeutics Limited AB (ATL), we purchased 15,025,075 shares of ATL's common stock that had a fair value \$0.095 per share, which was the quoted market price of the ATL common stock on the ASX (Australian Securities Exchange). As we may not contractually sell ATL's common shares for 24 months from the date of purchase, we estimated a discount for the lack of marketability of \$0.022 per share using an option pricing model that estimated the value of a protective put option using inputs that included quoted market prices and observable inputs other than quoted market prices. We recorded the net fair value amount of \$1.1 million as a non-current asset in our interim consolidated balance sheet.

Property and equipment, net

Property and equipment, net, consists of office equipment such as furniture, fixtures and computers. Depreciation expense for the six months ended June 30, 2014 and 2015 was not significant. The following amortization periods were used for the various classifications of property and equipment, net:

	<u>Amortization Periods</u>
Computer hardware	3-5 years
Computer software	2-5 years
Furniture and fixtures	2-5 years

Business combinations

When acquiring new enterprises over which we obtain control, the acquisition method is applied. Under this method, we identify assets and liabilities of these enterprises and measure them at fair value at the acquisition date. Allowance is made for the tax effect of the adjustments made.

The acquisition consideration for an enterprise consists of the fair value of the consideration paid for the acquired enterprise. Costs that are attributable to the acquisition of the enterprise are recognized in our statements of operations when incurred.

CORTENDO AB
(Predecessor of STRONGBRIDGE BIOPHARMA plc)

Notes to Interim Consolidated Financial Statements (Unaudited) (Continued)

In-process research and development

Purchased identifiable intangible assets with indefinite lives, such as our in-process research and development, are evaluated for impairment annually in accordance with our policy and whenever events or changes in circumstances indicate that it is more likely than not that the fair value of these assets has been reduced.

To test these assets for impairment, we compare the fair value of the asset to its carrying value. The method we use to estimate the fair value measurements of indefinite-lived intangible assets is based on the income approach.

Goodwill

We test goodwill for impairment on an annual basis or whenever events occur that may indicate possible impairment. This analysis requires us to make a series of critical assumptions to (1) evaluate whether any impairment exists and (2) measure the amount of impairment.

Because we have one operating segment, when testing for a potential impairment of goodwill, we are required to estimate the fair value of our business and determine the carrying value. If the estimated fair value is less than the carrying value of our business, then we are required to estimate the fair value of all identifiable assets and liabilities in a manner similar to a purchase price allocation for an acquired business. Only after this process is completed can the goodwill impairment be determined, if any.

When estimating the fair value of our business for the purposes of our annual analysis, we make estimates and judgments about the future cash flows of our businesses. Our cash flow forecasts are based on assumptions that are consistent with the plans and estimates we are using to manage the underlying business.

Research and development expenses

Research and development costs are expensed as incurred. Research and development expenses consist of internal and external expenses. Internal expenses include compensation and related expenses. External expenses include development, clinical trials, report writing and regulatory compliance costs incurred with clinical research organizations and other third-party vendors. At the end of the reporting period, we compare payments made to third-party service providers to the estimated progress toward completion of the research or development objectives. Such estimates are subject to change as additional information becomes available. Depending on the timing of payments to the service providers and the progress that we estimate has been made as a result of the service provided, we may record net prepaid or accrued expense relating to these costs. Upfront and milestone payments made to third parties who perform research and development services on our behalf are expensed as services are rendered.

Stock-based compensation

We account for stock-based compensation awards in accordance with FASB ASC Topic 718, Compensation—Stock Compensation (ASC 718). ASC 718 requires all stock-based payments including grants of stock options and restricted stock and modifications to existing stock options, to be recognized in the consolidated statements of operations based on their fair values.

Our stock-based awards are subject to either service-based or performance-based vesting conditions. Vesting of certain awards could also be accelerated upon achievement of defined market-

CORTENDO AB
(Predecessor of STRONGBRIDGE BIOPHARMA plc)

Notes to Interim Consolidated Financial Statements (Unaudited) (Continued)

based vesting conditions. We also have issued several stock options with exercise prices denominated in a foreign currency that are required to be accounted for as liabilities. We account for employee stock-based awards at grant-date fair value. We account for non-employee and liability-classified stock-based awards based on the then-current fair values at each financial reporting date until the performance is complete for non-employee awards, or until the award is settled (exercised) for liability-classified awards. Changes in the amounts attributed to these awards between the reporting dates are included in stock-based compensation expense (credit) in our statements of operations. We include liability-classified stock options into non-current liabilities in our balance sheets as their settlement (exercise) does not require use of cash, cash equivalents or other current assets.

We record compensation expense for service-based awards over the vesting period of the award on a straight-line basis. Compensation expense related to awards with performance-based vesting conditions is recognized over the requisite service period using the accelerated attribution method to the extent achievement of the performance condition is probable. Compensation expense for awards with service- and market-based vesting conditions is recognized using the accelerated attribution method over the shorter of the requisite service period or the implied period associated with achievement of the market-based vesting provisions.

We estimate the fair value of our option awards using the Black-Scholes option pricing model, which requires the input of subjective assumptions, including (i) the expected stock price volatility, (ii) the expected term of the award, (iii) the risk-free interest rate and (iv) expected dividends. Due to the lack of historical and implied volatility data of our common stock, we based our estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded. We selected companies with comparable characteristics to us, including enterprise value, risk profiles and position within the industry, and with historical share price information sufficient to meet the expected term of the stock-based awards. We compute historical volatility data using the daily closing prices for the selected companies' shares during the equivalent period of the calculated expected term of the stock-based awards.

We have estimated the expected term of employee service-based stock options using the "simplified" method, whereby the expected term equals the arithmetic average of the vesting term and the original contractual term of the option, due to our lack of sufficient historical data. We have estimated the expected term of employee awards with service and market conditions using a Monte-Carlo simulation model. This approach involves generating random stock-price paths through a lattice-type structure. Each path results in a certain financial outcome, such as accelerated vesting or specific option payout. We have estimated the expected term of nonemployee service- and performance-based awards based on the remaining contractual term of such awards.

The risk-free interest rates for periods within the expected term of the option are based on the Swedish Government Bond rate with a maturity date commensurate with the expected term of the associated award. We have never paid dividends, and do not expect to pay dividends in the foreseeable future.

We are also required to estimate forfeitures at the time of grant, and revise those estimates in subsequent periods if actual forfeitures differ from estimates. We record stock-based compensation expense only for those awards that are expected to vest. To the extent that actual forfeitures differ from our estimates, the differences are recorded as a cumulative adjustment in the period the estimates were revised. Historical forfeitures have been insignificant.

CORTENDO AB
(Predecessor of STRONGBRIDGE BIOPHARMA plc)

Notes to Interim Consolidated Financial Statements (Unaudited) (Continued)

Income taxes

We use the asset and liability method of accounting for income taxes in accordance with ASC Topic 740, Income Taxes. Under this method, income tax expense is recognized for the amount of (1) taxes payable or refundable for the current year and (2) deferred tax consequences of temporary differences resulting from matters that have been recognized in an entity's financial statements or tax returns.

Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in the results of operations in the period that includes the enactment date. A valuation allowance is provided to reduce the deferred tax assets reported if, based on the weight of the available positive and negative evidence, it is more likely than not some portion or all of the deferred tax assets will not be realized. ASC Topic 740.10.30 clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements and prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. ASC Topic 740.10.40 provides guidance on de-recognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. We have no material uncertain tax positions for any of the reporting periods presented.

We recognize interest and penalties related to uncertain tax positions in income tax expense. As of December 31, 2014 and June 30, 2015, we had no accrued interest or penalties related to uncertain tax positions and no amounts have been recognized in our interim statements of operations for the period ended June 30, 2014 and 2015.

Initial Public Offering (IPO) Costs

Incremental costs incurred that are directly attributable to a proposed or actual offering of securities are deferred and deducted from the related proceeds of the offering pursuant to ASC 340-10-s99-1 (SAB Topic 5A) "Expenses of the Offering." The net proceeds received are recorded as contributed shareholders' equity in the period when such shares are issued. As of June 30, 2015, the Company had deferred initial offering costs of \$1.3 million that are included in prepaid expenses and other current assets in the Company's interim consolidated balance sheet. These deferred costs will be charged to Strongbridge Biopharma plc and applied against the proceeds from Strongbridge Biopharma plc's initial public offering, when received.

Net loss per share

Basic net loss per share is calculated by dividing the net loss attributable to common stockholders by the weighted average number of shares of common stock outstanding during the period. Diluted net loss per share is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of common equivalent stock outstanding for the period, including any dilutive effect from outstanding stock options. Shares used in the diluted net loss per share calculations exclude anti-dilutive common equivalent shares, which consist of stock options. These anti-dilutive shares of common stock totaled 487,354 shares and 2,002,593 shares for the six months ended June 30, 2014 and 2015, respectively. While these common equivalent shares are currently anti-dilutive, they could be dilutive in the future.

CORTENDO AB
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Notes to Interim Consolidated Financial Statements (Unaudited) (Continued)

Subsequent events

We consider events or transactions that occur after the balances sheet date, but prior to the issuance of the financial statements to provided additional evidence relative to certain estimates or to identify matters that require additional disclosure.

Recently adopted accounting pronouncements

In April 2015, the FASB issued ASU No. 2015-05, *Customer's Accounting For Fees Paid In A Cloud Computing Arrangement*, which provides guidance for a customer's accounting for cloud computing costs. Under ASU 2015-05, if a software cloud computing arrangement contains a software license, customers should account for the license element of the arrangement in a manner consistent with the acquisition of other software licenses. If the arrangement does not contain a software license, customers should account for the arrangement as a service contract. This standard may be applied either prospectively to all arrangements entered into or materially modified after the effective date, or retrospectively. ASU 2015-05 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2015, and early adoption is permitted. The Company is currently evaluating the impact of the adoption of this standard on its consolidated financial statements.

3. Fair value measurement

The following table sets forth the fair value of our financial assets by level within the fair value hierarchy. Our foreign currency forward contracts are classified within Level II because of the use of observable inputs for similar derivative instruments in active markets, or quoted prices for identical or similar instruments in markets that are not active, and are directly or indirectly observable, and are classified as prepaid expenses and other current assets. The noncurrent receivable comprising of our investment in ATL common stock is classified as Level II as we discounted the active market quoted price of the security to reflect our contractual restriction on selling the investment. Our financial assets are as follows (in thousands):

	As of December 31, 2014			
	Level I	Level II	Level III	Total
Financial assets:				
Cash and cash equivalents	\$15,632	\$ —	\$—	\$15,632
Foreign currency forward contracts	\$ —	\$438	\$—	\$ 438
Total financial assets	<u>\$15,632</u>	<u>\$438</u>	<u>\$—</u>	<u>\$16,070</u>
	As of June 30, 2015			
	Level I	Level II	Level III	Total
Financial assets:				
Cash and cash equivalents	\$54,387	\$ —	\$—	\$54,387
Noncurrent receivable	\$ —	\$1,101	\$—	\$ 1,011
Total financial assets	<u>\$54,387</u>	<u>\$1,101</u>	<u>\$—</u>	<u>\$55,398</u>

CORTENDO AB
(Predecessor of STRONGBRIDGE BIOPHARMA plc)

Notes to Interim Consolidated Financial Statements (Unaudited) (Continued)

4. In-process research and development and goodwill

The following table presents in-process research and development and goodwill as of and during the six months ended June 30, 2015 (in thousands):

	<u>Balance at December 31, 2014</u>	<u>Additions</u>	<u>Disposals</u>	<u>Balance at June 30, 2015</u>
In-process research and development . . .	\$5,228	\$31,323	\$—	\$36,551
Goodwill	<u>2,200</u>	<u>5,056</u>	<u>—</u>	<u>7,256</u>
Total	<u>\$7,428</u>	<u>\$36,379</u>	<u>\$—</u>	<u>\$43,807</u>

Goodwill and in-process research and development as of December 31, 2014 and June 30, 2015, resulted from our acquisition of BioPancreate and our 2015 acquisition of product candidate DG3173 from Aspireo Pharmaceuticals, Ltd. (see also Note 7). In-process research and development is initially measured at its fair value and is not amortized until commercialization. Once commercialization occurs, in-process research and development will be amortized over its estimated useful life. We did not identify any indicators of impairment of our goodwill or in-process research and development as of June 30, 2015.

5. Accrued liabilities

Accrued liabilities consist of the following (in thousands):

	<u>December 31, 2014</u>	<u>June 30, 2015</u>
Consulting and professional fees	\$ 516	\$2,855
Employee compensation	804	531
Other	<u>102</u>	<u>117</u>
Total accrued liabilities	<u>\$1,422</u>	<u>\$3,503</u>

6. Commitments and contingencies

(a) Leases

On April 22, 2014, we entered into a 48-month building lease for approximately 3,000 square feet of space in Radnor, Pennsylvania. The lease has annual rent escalations. We obtained access to the newly leased space on August 1, 2014, and this was considered the lease commencement date for accounting purposes. Thus, rent expense began on this date and is recognized on a straight-line basis over the term of the lease.

In March 2015, the Company entered into a 52-month building sublease agreement for 14,743 square feet of office space in Trevese, Pennsylvania. As a result of this lease, we vacated the previously leased Radnor, Pennsylvania facility as of April 13, 2015 and determined that the facility was not likely to be utilized during the remaining lease term and as such we commenced efforts to sublease the facility. The Company recorded a liability as of the April 13, 2015 cease-use date of \$0.1 million for the estimated fair value of its obligations under the lease. The most significant assumptions used in determining the amount of the estimated liability are the potential sublease revenues and the credit-adjusted risk-free rate utilized to discount the estimated future cash flows.

CORTENDO AB
(Predecessor of STRONGBRIDGE BIOPHARMA plc)

Notes to Interim Consolidated Financial Statements (Unaudited) (Continued)

As of June 30, 2015, future minimum commitments under facility operating leases were as follows (in thousands):

	Operating leases
2015	\$ 175
2016	368
2017	394
2018	367
2019	184
Total minimum lease payments	<u>\$1,488</u>

Rent expense recognized under our operating lease, including additional charges for utilities, parking, maintenance and real estate taxes, was \$29 and \$111 for the six months ended June 30, 2014 and 2015, respectively.

(b) License Agreements

Our exclusive license agreement with ATL provides us with development and commercialization rights to ATLs' product candidate, ATL1103, for endocrinology applications. We refer to this product candidate as COR-004. Under the terms of the agreement, we paid ATL an initial upfront license fee of \$3.0 million in cash, and we also paid \$2.0 million for 15,025,075 shares of ATL common stock. On May 13, 2015, the date of the agreement, ATLs common stock had a fair value of \$0.095 per share, which was the quoted market price of the ATL common stock on the ASX (Australian Securities Exchange). As ATL is a publicly listed entity and under the terms of the agreement, we may not contractually sell ATL's common shares for 24 months from the date of purchase, we fair valued our investment and determined an estimated discount rate for the lack of marketability of \$0.022 per share using an option pricing model that estimated the value of a protective put option using inputs that included quoted market prices and observable inputs other than quoted market prices. We recorded the net amount of the ATL common stock of \$1.1 million as a non current asset in our consolidated balance sheet as at June 30, 2015. The difference between the amount paid for the ATL common stock of \$2.0 million and the fair value of the ATL common stock on the date of transaction of, \$1.1 million, has been recorded as research and development expense as of June 30, 2015, as we determined that the difference constitutes part of the cost of the license.

We may become obligated to make additional payments, contingent upon achieving specific development and commercialization milestones, of up to \$105.0 million over the lifetime of the agreement. We may also be required to make royalty payments based on a percentage, ranging from the mid-single digits to the mid-teens, of net sales of COR-004, if approved.

7. Business combinations

On June 30, 2015, we acquired from Aspireo Pharmaceuticals Ltd. ("Aspireo"), an Israeli company, its product candidate, DG3173, and the rights and obligations to the on-going research and development contracts, the combination of which represented "substantially all" of the Aspireo business. We refer to this product candidate as COR-005. Under the terms of the acquisition agreement, we issued to Aspireo 2,062,677 common shares, which had a value of \$33.2 million on June 30, 2015. In connection with this acquisition, we also made a payment to the Office of the Chief

CORTENDO AB
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Notes to Interim Consolidated Financial Statements (Unaudited) (Continued)

Scientist of the Israeli Ministry of Economy, or OCS, in the amount of \$3.0 million, which represents the repayment of amounts granted by the OCS to Aspireo, plus interest, that were used in support of research and development conducted by Aspireo for the development of DG3173.

The acquisition was accounted for using the acquisition method of accounting for business combinations. The total consideration transferred was allocated to the assets acquired and liabilities assumed based on their respective fair values. The fair value of \$14.54 per common share of the 2,062,677 ordinary shares issued was determined based on the closing market price on the NOTC of our common shares on the acquisition date. To determine the fair value of the acquired in-process research and development intangible asset, we applied the income approach using the multi-period excess earnings method. The following table summarizes the estimated fair values of the assets acquired and liabilities assumed (in thousands):

In process research and development	\$ 31,323
Liabilities assumed:	
Other liabilities (net)	(195)
OCS liability	<u>(2,973)</u>
Total fair values of assets and liabilities	28,155
Fair value of total consideration transferred	<u>(33,211)</u>
Goodwill	<u>\$ 5,056</u>

The excess of the consideration transferred over net assets acquired was assigned to goodwill in an amount of \$5.1 million and is primarily related to expected synergies. A deferred tax liability was not recorded for the difference between the book and cost basis of the in-process research and development intangible asset because this will be domiciled in the Cayman Islands and therefore we do not expect to pay income tax. The goodwill is not deductible for income tax purposes.

We incurred \$2.6 million in acquisition-related transaction costs for the period ended June 30, 2015, which is included as general and administration expense in the accompanying unaudited interim consolidated statements of operations.

8. Income taxes

For the six month periods ended June 30, 2014 and 2015, we recorded income tax benefits of \$225,000 and \$178,000, respectively. We recorded tax benefits for the federal and state net operating loss carry forwards and federal tax credit carryforwards attributable to BioPancreate. These deferred benefits are realizable as they offset the non-current deferred tax liability recorded in connection with the acquisition of BioPancreate.

We have incurred net operating losses since inception. We have not reflected any benefit of net operating loss carryforwards (NOLs), other than those attributable to BioPancreate, in the accompanying financial statements. We have established a valuation allowance against the remaining deferred tax assets due to the uncertainty surrounding the realization of such assets.

CORTENDO AB
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Notes to Interim Consolidated Financial Statements (Unaudited) (Continued)

9. Common stock

Voting rights and privileges

The holders of shares of our common stock are entitled to one vote for each share of common stock held at all meetings of stockholders without limitation and written actions in lieu of meetings. The holders are entitled to receive dividends if and when declared by our Board of Directors. No dividends have been declared or paid since our inception. The holders are entitled to share ratably in our assets available for distribution to stockholders, in the event of any voluntary or involuntary liquidation.

Equity financings

In December 2014, we issued 1,755,909 shares of common stock for \$10.2 million, net of transaction costs.

On February 10, 2015, following shareholder approval of the share purchase agreement which we entered into on January 12, 2015, we issued 4,761,078 shares of our common stock for \$25.8 million, net of transaction costs.

On June 29 and 30, 2015, following shareholder approval of the share purchase agreement which we entered into on May 14, 2015, we issued 2,284,414 new shares to the investors. The subscription price was \$14.54 per share and proceeds net of transaction costs were \$32.6 million.

Shares reserved for issuance

There were 925,077 and 2,002,593 shares of common stock reserved for future issuance upon exercise of stock options as of December 31, 2014 and June 30, 2015, respectively.

10. Stock-based compensation

Our Board of Directors and our shareholders approve the granting of stock options to our officers, directors, other key employees and third party-consultants. Under these grants, the beneficiaries are given the right to acquire new shares of common stock at a pre-determined option price. The purpose of the grants is to assist us in attracting, retaining and motivating officers, employees, directors and consultants. In addition, these awards provide us with the ability to provide incentives that are directly linked to the performance of our business and the related increase in shareholder value.

Stock options grants have a maximum term of five years. As determined by our Board of Directors, our stock-based awards vest over periods ranging up to four years or upon achievement of defined performance criteria. In addition, vesting of certain awards could be accelerated when the fair value of our stock reaches defined targets.

The exercise price for each stock option is determined by the Board of Directors based upon considerations such as the fair value of the underlying common stock and certain market conditions. The determination of the fair value of our common stock takes into account the price at which our shares are being traded on the NOTC, recent equity financings and third-party valuations.

CORTENDO AB
(Predecessor of STRONGBRIDGE BIOPHARMA plc)

Notes to Interim Consolidated Financial Statements (Unaudited) (Continued)

A summary of the outstanding stock options as of June 30, 2015 is as follows:

	Options Outstanding			
	Number of Shares	Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in thousands)
Outstanding—December 31, 2014	925,077	\$ 8.01	3.72	\$1,011
Granted	1,079,788	\$16.15		
Forfeited	(2,272)	\$ 9.87		
Exercised				
Outstanding—June 30, 2015	<u>2,002,593</u>	\$12.40	\$4.72	\$6,904
Vested and exercisable—June 30, 2015	<u>487,354</u>	\$ 4.39	2.22	\$5,298
Vested and expected to vest—June 30, 2015	<u>2,002,593</u>	\$12.40	4.72	\$6,904

Included in the options outstanding at June 30, 2015 are stock options to purchase 299,999 shares at a weighted average exercise price of \$3.01 per share accounted for as liabilities, which were fully vested as of June 30, 2015, and stock options to purchase 436,360 shares at a weighted average exercise price of \$11.88 per share which are subject to acceleration if the fair value per share of our stock reaches 132 Norwegian Kroner (\$17.71 at June 30, 2015 adjusted for the reverse stock split) and 218,178 shares at a weighted average exercise \$15.08 per share which are subject to acceleration if the fair value per share of our stock reaches 165 Norwegian Kroner (\$20.02 at June 30, 2015 adjusted for the reverse stock split), of which were all unvested as of June 30, 2015. In addition, the options outstanding include 205,906 options that will vest when we begin trading on Nasdaq, provided that such trading date occurs prior to May 26, 2017, 102,951 shares that vest upon a market appreciation event so long as it occurs prior to May 26, 2019 and 102,951 shares that will vest upon the one year anniversary of the market appreciation event. The market appreciation event is defined as the last trading day in the period in which the closing stock price on each of 20 consecutive trading days reported on NASDAQ has been at least \$33.66.

The aggregate intrinsic values of options outstanding, vested and exercisable, and vested and expected to vest were calculated as the difference between the exercise price of the options and the estimated fair value of our ordinary shares as of December 31, 2014 and June 30, 2015, respectively.

CORTENDO AB
(Predecessor of STRONGBRIDGE BIOPHARMA plc)

Notes to Interim Consolidated Financial Statements (Unaudited) (Continued)

Stock-based compensation expense

We recognized stock-based compensation expense for employees and non-employees in the accompanying consolidated statements of operations as follows (in thousands):

	Six Months Ended June 30,	
	2014	2015
Research and development	\$ 58	\$ 947
General and administrative	88	1,872
Total stock-based compensation	<u>\$146</u>	<u>\$2,819</u>

Included in these amounts was stock compensation expense (credit) attributed to liability-classified awards of \$(0.0) and \$ 2.3 million, for the six months ended June 30, 2014 and 2015, respectively. As of June 30, 2015, the total unrecognized compensation expense related to unvested options, net of estimated forfeitures, was \$3.4 million, which we expect to recognize over an estimated weighted-average period of 1.75 years.

In determining the estimated fair value of the stock-based awards, we use the Black-Scholes option-pricing model and assumptions discussed below. Each of these inputs is subjective and generally requires significant judgment to determine.

The fair value of stock option awards was estimated with the following assumptions:

	Six Months Ended June 30,	
	2014	2015
Expected term (in years)	3.23	5.92
Risk-free interest rate	0.0%-0.6%	(0.2)%-0.6%
Expected volatility	68.3%-80.7%	70.9%-73.4%
Dividend rate	0%	0%

UNAUDITED PRO FORMA CONDENSED COMBINED FINANCIAL STATEMENTS

Introduction

On May 14, 2015, we entered into an asset purchase agreement with Aspireo and TVM V Life Science Venture GmbH & Co. KG (TVM) to acquire all rights in and obligations of the Somatoprim program (the Program) of Aspireo, for the treatment of acromegaly and which also has potential additional applications for the treatment of endogenous Cushing's syndrome and neuroendocrine tumors. The asset purchase agreement was approved by our shareholders on June 25, 2015, and the transaction closed on June 30, 2015.

The following unaudited pro forma condensed combined financial statements and related notes present our historical condensed combined financial information and that of Aspireo after giving effect to our acquisition of the Program, and are based on the assumptions and adjustments described in the accompanying notes to the unaudited pro forma condensed combined financial statements.

The unaudited pro forma condensed combined balance sheet of Strongbridge Biopharma plc is not presented, as the acquisition of the Program was completed on June 15, 2015 and is reflected in the unaudited interim consolidated financial statements of Cortendo AB, our predecessor presented elsewhere in this Registration Statement. The unaudited interim consolidated balance sheet of Cortendo AB at June 30, 2015 is materially the same as balance sheet at the same date. The unaudited pro forma condensed combined statement of operations for the six months ended June 30, 2015 and for the year ended December 31, 2014 are presented as if the acquisition of the Program had occurred on January 1, 2014. The historical financial information is adjusted in the unaudited pro forma condensed combined financial statements to give effect to pro forma events that are (1) directly attributable to the acquisition of the Program, (2) factually supportable, and (3) expected to have a continuing impact on the combined results of operations.

We have accounted for the acquisition of the Program in these unaudited pro forma condensed combined financial statements using the acquisition method of accounting in accordance with Financial Accounting Standards Board Accounting Standards Codification Topic 805 "Business Combinations" (ASC 805). In accordance with ASC 805, we use our best estimates and assumptions to assign fair value to the tangible and intangible assets acquired and liabilities assumed at the acquisition date. Goodwill as of the acquisition date is measured as the excess of purchase consideration over the fair value of the identifiable net assets acquired.

The pro forma adjustments described below were developed based on our management's assumptions and estimates, including assumptions relating to the consideration paid and the fair values of the assets acquired from Aspireo and the liabilities assumed based on preliminary estimates.

The determination and preliminary allocation of the purchase consideration used in the unaudited pro forma condensed combined financial statements are based upon preliminary estimates, which are subject to change as we finalize the valuations of the intangible assets acquired.

Our statement of operations information for the six months ended June 30, 2015 and the year ended December 31, 2014 were derived from our unaudited interim consolidated financial statements and our audited consolidated financial statements, respectively.

The Aspireo statement of operation information for the six months ended June 30, 2015 and for the year ended December 31, 2014 were derived from its June 30, 2015 unaudited financial statements and its December 31, 2014 audited financial statements, which have been prepared in accordance with International Financial Reporting Standards as issued by the International Accounting Standards Board (IFRS). The consolidated financial statements have been converted to U.S. generally accepted accounting principles (U.S. GAAP), and translated from Euro into U.S. Dollars, for purposes

of presentation in the unaudited pro forma condensed combined financial statements. There are no material IFRS to U.S. GAAP differences requiring adjustment.

The unaudited pro forma condensed combined financial statements do not give effect to the potential impact of current financial conditions, regulatory matters, anticipated synergies, operating efficiencies or cost savings that may be associated with the acquisition of the Program. The unaudited pro forma condensed combined financial statements also do not include any integration costs. The unaudited pro forma condensed combined financial statements have been prepared for illustrative purposes only and are not necessarily indicative of the financial position or results of operations in future periods or the results that actually would have been realized had we been a combined company during the specified period. The unaudited pro forma condensed combined financial statements, including the notes thereto, should be read in conjunction with our historical financial statements, and the historical financial statements of Aspireo for the six months ended June 30, 2015 and for the years ended December 31, 2014 and 2013, all of which are included in this Registration Statement.

STRONGBRIDGE BIOPHARMA plc (formerly Cortendo plc)
Unaudited Pro Forma Condensed Combined Statement of Operations
For the Six Months Ended June 30, 2015
(In thousands, except share and per share data)

	Historical		Aspireo Acquisition		Pro Forma Combined
	Strongbridge Biopharma plc	Aspireo ⁽¹⁾			
Operating expenses:					
Research and development	10,218	273	—		\$ 10,491
General and administrative	12,620	826	(335)	A	13,111
Gain on sale of Somatoprim program, net	—	(37,218)	37,218	B	—
Total operating expenses	22,838	(36,119)	36,883		23,602
Operating loss	(22,838)	36,119	(36,883)		(23,602)
Other income (expense), net:					
Foreign exchange loss	(314)		—		(314)
Other, net	(543)	(651)			(1,194)
Total other income (expense), net	(857)	(651)	—		(1,508)
Income before income taxes	(23,695)	35,468	(36,883)		(25,110)
Income tax benefit	178				178
Net loss	\$ (23,517)	\$ 35,468	\$(36,883)		\$ (24,932)
Net loss attributable to common stockholders:					
Basic and diluted	\$ (23,517)	\$ 35,468	\$(36,883)		\$ (24,932)
Net loss per share attributable to common stockholders:					
Basic and diluted	\$ (1.75)				\$ (1.52)
Weighted-average shares used in computing net loss per share attributable to common stockholders:					
Basic and diluted	13,433,712				15,496,389

(1) Aspireo historical financial statements have been prepared using its functional currency of Euro. For purposes of these unaudited pro forma financial statements, the Aspireo statement of operations has been translated into U.S. dollars using the average conversion rate in effect during 2014 (1.1630).

See accompanying notes to the unaudited pro forma condensed combined financial statements

STRONGBRIDGE BIOPHARMA plc (formerly Cortendo plc)
Unaudited Pro Forma Condensed Combined Statement of Operations (Continued)
For the Year Ended December 31, 2014
(In thousands, except share and per share data)

	Historical		Aspireo Acquisition		Pro Forma Combined
	Strongbridge Biopharma plc	Aspireo ⁽¹⁾			
Operating expenses:					
Research and development	5,844	880	—		\$ 6,724
General and administrative	4,588	1,380	(86)	A	5,882
Other expense	—	2,762	—		2,762
Total operating expenses	10,432	5,022	(86)		15,368
Operating loss	(10,432)	(5,022)	86		(15,368)
Other income (expense), net:					
Foreign exchange loss	(204)	(9)	—		(213)
Other, net	486	(4)	—		482
Total other income (expense), net	282	(13)	—		269
Income before income taxes	(10,150)	(5,035)	86		(15,099)
Income tax benefit	(480)	—	—		(480)
Net loss	\$ (9,670)	\$(5,035)	\$ 86		\$ (14,619)
Net loss attributable to common stockholders:					
Basic and diluted	\$ (9,670)	\$(5,035)	\$ 86		\$ (14,619)
Net loss per share attributable to common stockholders:					
Basic and diluted	\$ (1.20)				\$ (0.96)
Weighted-average shares used in computing net loss per share attributable to common stockholders:					
Basic and diluted	8,043,175				10,105,852

(1) Aspireo historical financial statements have been prepared using its functional currency of Euro. For purposes of these unaudited pro forma financial statements, the Aspireo statement of operations has been translated into U.S. dollars using the average conversion rate in effect during 2014 (1.3290).

See accompanying notes to the unaudited pro forma condensed combined financial statements

STRONGBRIDGE BIOPHARMA plc (formerly Cortendo plc)

**Notes to Unaudited Pro Forma Condensed
Combined Financial Statements**

1. Pro Forma Adjustments

The pro forma adjustments included in the unaudited pro forma condensed combined financial statements are as follows:

- A. To eliminate Aspireo's historical stock-based compensation expense for the six months ended June 30, 2015 and the year ended December 31, 2014, respectively.
- B. To eliminate the gain on the sale of the Somatoprim program recognized by Aspireo.



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REPORT OF INDEPENDENT AUDITORS

To the Shareholders of Aspireo Pharmaceuticals Limited

We have audited the accompanying financial statements of Aspireo Pharmaceuticals Limited, which comprise the statements of financial position as of December 31, 2014 and 2013, and January 1, 2013 and the related statements of profit or loss, changes in equity and of cash flows for each of the two years in the period ended December 31, 2014, and the related notes to the financial statements.

Management's Responsibility for the Financial Statements

Management is responsible for the preparation and fair presentation of these financial statements in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board; this includes the design, implementation and maintenance of internal controls relevant to the preparation and fair presentation of financial statements that are free of material misstatement, whether due to fraud or error.

Auditor's Responsibility

Our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits in accordance with auditing standards generally accepted in the United States. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the financial statements. The procedures selected depend on the auditor's judgment, including the assessment of the risks of material misstatement of the financial statements, whether due to fraud or error. In making those risk assessments, the auditor considers internal controls relevant to the entity's preparation and fair presentation of the financial statements in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the entity's internal control. Accordingly, we express no such opinion. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of significant accounting estimates made by management, as well as evaluating the overall presentation of the financial statements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

Opinion

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Aspireo Pharmaceuticals Limited at December 31, 2014, 2013, and January 1, 2013, and the results of its operations and its statements of cash flows for each of the two years in the period ended December 31, 2014, in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board.

As discussed in note 1(c) to the financial statements, following the closing of the Asset Purchase Agreement on June 30, 2015 the Company has no principal operational activity except for the holding of the shares of Cortendo AB which received as consideration for the sale of its Somatoprim program.

August 13, 2015
Tel-Aviv, Israel

/s/ KOST FORER GABBAY & KASIERER
A Member of Ernst & Young Global

ASPIREO PHARMACEUTICALS LTD.
STATEMENTS OF FINANCIAL POSITION
Euro in thousands

	Year Ended December 31,		January 1, 2013 (first time adoption of IFRS)
	2014	2013	EURO
	EURO		EURO
ASSETS			
CURRENT ASSETS:			
Cash and cash equivalents	752	1,329	1,022
Other receivables and prepaid expenses	<u>96</u>	<u>15</u>	<u>16</u>
Total current assets	<u>848</u>	<u>1,344</u>	<u>1,038</u>
NON-CURRENT ASSETS:			
Property and equipment, net	<u>2</u>	<u>3</u>	<u>2</u>
Total non-current assets	<u>2</u>	<u>3</u>	<u>2</u>
TOTAL ASSETS	<u>850</u>	<u>1,347</u>	<u>1,040</u>

The accompanying notes are an integral part of the financial statements.

ASPIREO PHARMACEUTICALS LTD.
STATEMENTS OF FINANCIAL POSITION (Continued)
Euro in thousands

	Year Ended December 31,		January 1,
	2014	2013	2013
	EURO		EURO
LIABILITIES AND SHAREHOLDERS' EQUITY (DEFICIENCY)			
CURRENT LIABILITIES:			
Trade payables	76	91	118
Other payables and accrued expenses	2,297	56	281
Total current liabilities	2,373	147	399
COMMITMENTS AND CONTINGENCIES			
EQUITY ATTRIBUTABLE TO SHAREHOLDERS' OF THE COMPANY:			
Share capital	7,041	6,682	5,978
Share premium	67,655	66,949	65,543
Retained earnings (deficit)	(76,219)	(72,431)	(70,880)
Total equity (deficiency)	(1,523)	1,200	641
Total liabilities and shareholders' equity (deficiency)	850	1,347	1,040

The accompanying notes are an integral part of the financial statements.

ASPIREO PHARMACEUTICALS LTD.
STATEMENTS OF PROFIT OR LOSS
Euro in thousands (except share and per share data)

	Year Ended	
	December 31,	
	2014	2013
	EURO	
Operating expenses:		
Research and development	662	631
General and administrative	1,038	908
Other expenses	2,078	—
Total operating expenses	<u>3,778</u>	<u>1,539</u>
Operating loss	3,778	1,539
Finance expenses, net	<u>10</u>	<u>12</u>
Net loss	<u><u>3,788</u></u>	<u><u>1,551</u></u>

The accompanying notes are an integral part of the financial statements.

ASPIREO PHARMACEUTICALS LTD.
STATEMENTS OF CHANGES IN EQUITY
Euro in thousands (except share data)

	<u>Number of Ordinary Shares</u>	<u>Amount</u>	<u>Share premium</u>	<u>Retained deficit</u>	<u>Equity (Deficiency) attributable to shareholders of the Company</u>
Balance as of January 1, 2013	294,972,746	5,978	65,543	(70,880)	641
Issuance of ordinary shares to parent					
Company	31,796,502	666	1,333	—	1,999
Share based payment transactions	1,850,590	38	73	—	111
Net loss	—	—	—	(1,551)	(1,551)
Balance as of December 31, 2013	328,619,838	6,682	66,949	(72,431)	1,200
Issuance of ordinary shares to parent					
Company	15,898,252	339	661	—	1,000
Share based payment transactions	925,296	20	45	—	65
Net loss	—	—	—	(3,788)	(3,788)
Balance as of December 31, 2014	<u>345,443,386</u>	<u>7,041</u>	<u>67,655</u>	<u>(76,219)</u>	<u>(1,523)</u>

The accompanying notes are an integral part of the financial statements.

ASPIREO PHARMACEUTICALS LTD.
STATEMENTS OF CASH FLOWS
Euro in thousands

	Year Ended December 31,	
	2014	2013
	EURO	
<i>Cash flows from operating activities:</i>		
Net loss	(3,788)	(1,551)
Adjustments to reconcile net loss to net cash used in operating activities:		
Adjustments to the profit or loss items:		
Depreciation of equipment	1	2
Share-based payment transactions	65	111
Changes in assets and liabilities:		
Decrease (increase) in receivables and prepaid expenses	(81)	1
Decrease in trade payables	(15)	(28)
Increase (decrease) in other payables and accrued expenses	<u>2,241</u>	<u>(224)</u>
Net cash used in operating activities	<u>(1,577)</u>	<u>(1,689)</u>
<i>Cash flows from investing activities:</i>		
Purchase of equipment	<u>—</u>	<u>(3)</u>
Net cash used in investing activities	<u>—</u>	<u>(3)</u>
<i>Cash flows from financing activities:</i>		
Issuance of share capital to parent company	<u>1,000</u>	<u>1,999</u>
Net cash provided by financing activities	<u>1,000</u>	<u>1,999</u>
Increase (decrease) in cash and cash equivalents	(577)	307
Cash and cash equivalents at the beginning of the year	<u>1,329</u>	<u>1,022</u>
Cash and cash equivalents at the end of the year	<u><u>752</u></u>	<u><u>1,329</u></u>

The accompanying notes are an integral part of the financial statements.

ASPIREO PHARMACEUTICALS LTD.
NOTES TO FINANCIAL STATEMENTS
Euro in thousands (except share and per share data)

NOTE 1:- CORPORATE INFORMATION:

- a. Aspireo Pharmaceuticals Limited (the “Company”) was established in 1992 and started activities in 1993. The Company was previously engaged in research and development of treatments for diabetes, autoimmune diseases and other research programs and since 2010, the Company is focused solely on the development of somatostatin analogs for the potential treatment of acromegaly, Cushing’s disease, carcinoid tumors and diabetic retinopathy.

TVM V Life Science Ventures GmbH & Co KG. is the parent company.

The Company sole development compound is Somatoprim (DG3173), a proprietary somatostatin analog that is based on a novel amino acid composition and a unique backbone cyclization technology used for stabilization of the peptide.

The Company’s activities since inception have consisted principally of raising capital and performing research and development activities. Successful completion of the Company’s development programs and, ultimately, the attainment of profitable operations are dependent on future events, including, among other things, its ability to obtain regulatory approval from regulatory authorities and access potential markets; secure financing, develop a customer base; attract, retain and motivate qualified personnel; and develop strategic alliances. Although management believes that the Company will be able to successfully fund its operations, there can be no assurance that the Company will be able to do so or that the Company will ever operate profitably.

The financial statements of the Company for the year ended December 31, 2014 were approved by the Board of Directors on June 10, 2015.

- b. As of December 31, 2014, the Company had cash and cash equivalents of Euro 752. During the year ended December 31, 2014 the Company incurred a net loss of Euro 3,788 and had negative cash flows from operating activities of Euro 1,577. In addition, the Company had a retained deficit of Euro 76,219 at December 31, 2014.

Management intends to finance operations of the Company through equity financings. Company’s management has received a letter of support from its parent company in which it confirmed that it will assist the Company to meet its liabilities at least until December 31, 2015, as and when they fall due but only to the extent that money is not otherwise available to meet such liabilities.

- c. On May 14, 2015, the Company entered into an Asset Purchase Agreement (“APA”) with Cortendo AB (“Cortendo”), a Swedish company listed in Norway—NOTC, regarding the purchase by Cortendo of Aspireo’s Somatoprim (DG3173) program. Under the terms of the agreement, Cortendo acquired all rights and obligations in the Somatoprim program and assumed responsibility for the further development and commercialization of the Somatoprim program. As consideration for the sale, Aspireo received 22,689,456 shares in Cortendo. The number of shares was determined based on the fair value of Cortendo shares on the date of signing the APA. In addition, Cortendo also assumed the OCS liability (see Note 8).

Management believes that as of June 30, 2015, all closing conditions of the APA were met. The fair value of the shares on the close date was approximately \$33 million (see Note 13a).

ASPIREO PHARMACEUTICALS LTD.
NOTES TO FINANCIAL STATEMENTS (Continued)
Euro in thousands (except share and per share data)

Following the closing of the Asset Purchase Agreement on June 30, 2015 the Company has no principal operational activity except for the holding of the shares of Cortendo which received as consideration for the sale of its Somatoprim program.

The disposal of substantially all of the operations of the Company does not qualify as a discontinued operation under IFRS 5.

d. The financial statements of the Company have been prepared in accordance with International Financial Reporting Standards (IFRS) as issued by the International Accounting Standards Board (IASB). For all periods up to and including the year ended December 31, 2012, the Company prepared its financial statements in accordance with Israeli generally accepted accounting principles (Israeli GAAP). The financial statements for the year ended December 31, 2014 are the first statements Company has prepared in accordance with IFRS. Refer to Note 2k for information on adoption of IFRS by the Company.

e. Basis of presentation of the financial statements:

The Company's financial statements have been prepared on a historical cost basis. The Company has elected to present profit or loss items using the function of expenses method.

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES

The following are the significant accounting policies applied by the Company in preparing its financial statements:

a. Fair value measurement

Fair value is the price that would be received for selling an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The fair value measurement is based on the assumption that the transaction to sell the asset or transfer the liability takes place either in the principal market for the asset or liability or in the absence of a principal market, in the most advantageous market for the asset or liability.

The principal or the most advantageous market must be accessible by the Company. As of December 31, 2014 and 2013 no financial instruments were measured at fair value.

b. Functional currency, presentation currency and foreign currency transactions:

1. Functional currency and presentation currency:

The Company's functional currency is the Euro and the financial statements are presented in Euro.

2. Transactions, assets and liabilities in foreign currency and balances:

Transactions denominated in foreign currencies are initially recorded by the Company at the date the transaction first qualifies for recognition. Monetary assets and liabilities denominated in foreign currencies are retranslated to Euros using the spot rate at the reporting date.

Differences arising on settlement or translation of monetary items are recognised in profit or loss. Non-monetary items denominated in foreign currency and that are measured in terms of historical cost in a foreign currency are translated using the exchange rates as at the dates of the initial transactions.

ASPIREO PHARMACEUTICALS LTD.
NOTES TO FINANCIAL STATEMENTS (Continued)
Euro in thousands (except share and per share data)

c. Government grants

In connection with its research and development programs, until 2003, the Company received and accrued participation payments from the Office of the Chief Scientist of the Ministry of Economy in Israel ("OCS").

Government grants are recognized where there is reasonable assurance that the grant will be received and the Company will comply with the attached conditions.

Government grants received from OCS as support for research and development projects include an obligation to pay royalties that are conditional on future sales arising from the project. The grants are recognized upon receipt as a liability if future economic benefits are expected from the project. If no such economic benefits are expected, the grants are recognized as a reduction of the related research and development expenses. In that event, the royalty obligation is treated as a contingent liability in accordance with IAS 37.

At the end of each reporting period, the Company evaluates, based on its best estimate of future economic benefits, whether there is reasonable assurance that the liability recognized, in whole or in part, will not have to be repaid. If there is such reasonable assurance, the appropriate amount of the liability is derecognized and recorded in profit or loss as a reduction of research and development expenses. If the estimate of future economic benefits indicates that there is no such reasonable assurance, the appropriate amount of the liability that reflects expected future royalty payments is recognized with a corresponding adjustment to other expenses (see also Note 3 and Note 8).

d. Financial liabilities

The Company's financial liabilities include trade and other payables are recognised initially at fair value.

e. Taxes

Current income tax

Current income tax assets and liabilities for the current period are measured at the amount expected to be recovered from or paid to the taxation authorities. The tax rates and tax laws used to compute the amount are those that are enacted or substantively enacted, at the reporting date.

Management periodically evaluates positions taken in the tax returns with respect to situations in which applicable tax regulations are subject to interpretation and establishes provisions where appropriate.

Deferred tax

Deferred tax is provided using the liability method on temporary differences between the tax bases of assets and liabilities and their carrying amounts for financial reporting purposes at the reporting date.

Deferred tax assets are recognised for all deductible temporary differences, carry forward of unused tax credits and unused tax losses, to the extent that it is probable that taxable profit will be available against which the deductible temporary differences, and the carry forward of unused tax credits and unused tax losses can be utilized.

ASPIREO PHARMACEUTICALS LTD.
NOTES TO FINANCIAL STATEMENTS (Continued)
Euro in thousands (except share and per share data)

The carrying amount of deferred tax assets is reviewed at each reporting date and reduced to the extent that it is no longer probable that sufficient taxable profit will be available to allow all or part of the deferred tax asset to be utilised. Unrecognised deferred tax assets are reassessed at each reporting date and are recognised to the extent that it has become probable that future taxable profits will allow the deferred tax asset to be recovered.

Deferred tax assets and liabilities are measured at the tax rates that are expected to apply in the year when the asset is realised or the liability is settled, based on tax rates (and tax laws) that have been enacted or substantively enacted at the reporting date.

f. **Property and Equipment**

Property and equipment is stated at cost, net of accumulated depreciation and accumulated impairment losses, if any.

Depreciation is calculated on a straight-line basis over the estimated useful lives of the assets, as follows:

- Computer and Software up to 3 years

An item of property and equipment and any significant part initially recognised is derecognised upon disposal or when no future economic benefits are expected from its use or disposal. Any gain or loss arising on derecognition of the asset (calculated as the difference between the net disposal proceeds and the carrying amount of the asset) is included in the statement of profit or loss when the asset is derecognised.

The residual values, useful lives and methods of depreciation of property and equipment are reviewed at each financial year end and adjusted prospectively, if appropriate.

g. **Research and Development Costs**

Research and development costs are expensed as incurred since not all of the following conditions have been met or fulfilled:

- The technical feasibility of completing the project so that it will be available for use or sale
- Its intention to complete and its ability to use or sell the asset
- How the asset will generate future economic benefits
- The availability of resources to complete the asset
- The ability to reliably measure the expenditure during development

h. **Cash and cash equivalents**

Cash and cash equivalents in the statements of financial position comprise cash at banks and on hand with a maturity of three months or less.

i. **Provisions**

Provisions are recognised when the Company has a present obligation (legal or constructive) as a result of a past event, it is probable that an outflow of resources embodying economic benefits will be required to settle the obligation and a reliable estimate can be made of the amount of the obligation.

ASPIREO PHARMACEUTICALS LTD.
NOTES TO FINANCIAL STATEMENTS (Continued)
Euro in thousands (except share and per share data)

j. Share-based payment transactions

The cost of share based payments is determined by the fair value at the date when the grant is made using an appropriate valuation model.

The cost of share based payment is recognised together with a corresponding increase in share premium in equity over the period in which the service conditions are fulfilled. The cumulative expense recognised for share based payments at each reporting date until the vesting date, reflects the extent to which the vesting period has expired and the Company's best estimate of the number of equity instruments that will ultimately vest.

k. First-time adoption of IFRS

Historically, the Company prepared its financial statement in accordance with Israeli GAAP. The Company's management has elected to adopt IFRS and the Company's opening Statement of Financial Position is January 1, 2013 (the transition date).

The Company uses the same accounting policies in its opening Statement of Financial Position and throughout all periods presented in its first IFRS financial statements.

Exemption applied

IFRS 1 allows first-time adopters certain exemptions from the retrospective application of certain requirements under IFRS.

The Company has applied the following exemption:

- Cumulative currency translation differences between the functional currency and the reporting currency are deemed to be zero as at January 1, 2013.

Estimates and assumptions

The estimates at January 1, 2013 and at December 31, 2013 are consistent with those made for the same dates in accordance with Israeli GAAP (after adjustments to reflect any differences in accounting policies). The estimates used by the Company to present these amounts in accordance with IFRS reflect conditions at January 1, 2013, the date of transition to IFRS, and as of December 31, 2013.

Company Reconciliation of Equity as of January 1, 2013 and December 31, 2013 and Statements of Profit or Loss for the year ended December 31, 2013:

There were no material remeasurements required in order to reconcile Israeli GAAP financial statements to IFRS, after applying the relevant exemption above.

Notes to the reconciliation of equity as at January 1, 2013 and December 31, 2013 and net loss for the year ended December 31, 2013:

Share-based payments

Both IFRS and Israeli GAAP require that the fair value of the granted shares be determined using an appropriate pricing model recognized over the vesting period. Previously, the Company did not record the compensation as expenses under Israeli GAAP.

ASPIREO PHARMACEUTICALS LTD.
NOTES TO FINANCIAL STATEMENTS (Continued)
Euro in thousands (except share and per share data)

Upon transition to IFRS, a compensation expense of Euro 111 has been recognised in the Statements of Profit or Loss for the year ended December 31, 2013 and an amount of Euro 676 was recognised as share premium as of January 1, 2013.

Foreign currency translation

Under Israeli GAAP, the Company recognised translation differences between the functional currency and the reporting currency as a separate component of equity. Cumulative currency translation differences for all the periods are deemed to be zero as of January 1, 2013. The resulting adjustment was recognised against retained earnings.

Statement of cash flows

The transition from Israeli GAAP to IFRS has not had an impact on the Statements of Cash Flows.

NOTE 3:- SIGNIFICANT ACCOUNTING JUDGEMENTS, ESTIMATES AND ASSUMPTIONS

The preparation of the Company's financial statements requires management to make judgements, estimates and assumptions that affect the reported amounts of expenses, assets and liabilities, and the accompanying disclosures, and the disclosure of contingent liabilities. Uncertainty about these assumptions and estimates could result in outcomes that require a material adjustment to the carrying amount of the asset or liability affected in future periods.

Judgements

In the process of applying the Company's accounting policies, management has made the following judgements, which have the most significant effect on the amounts recognised in the financial statements:

Estimates and assumptions

The key assumptions concerning the future and other key sources of estimation uncertainty at the reporting date, that have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next financial year, are described below. The Company based its assumptions and estimates on parameters available when the financial statements were prepared. Existing circumstances and assumptions about future developments, however, may change due to market changes or circumstances arising beyond the control of the Company. Such changes are reflected in the assumptions when they occur.

Grants from the Office of the Chief Scientist:

Government grants received from the OCS are recognized as a liability if future economic benefits are expected from the research and development activity that will result in royalty-bearing sales. There is uncertainty regarding the timing and the estimated future cash flows used to measure the amount of the liability.

ASPIREO PHARMACEUTICALS LTD.
NOTES TO FINANCIAL STATEMENTS (Continued)
Euro in thousands (except share and per share data)

Share-based payments

The Company measures the cost of equity-settled transactions by reference to the fair value of the equity instruments at the date at which they are granted. The fair value of the Company's shares was determined by the Company's management with the assistance of third party appraiser.

Deferred tax assets

Deferred tax assets are recognized for unused carryforward tax losses and deductible temporary differences to the extent that it is probable that taxable profit will be available against which the losses can be utilized. Significant management judgment is required to determine the amount of deferred tax assets that can be recognized, based upon the timing and level of future taxable profits, its source and the tax planning strategy.

NOTE 4:- STANDARDS ISSUED BUT NOT YET EFFECTIVE

The standards and interpretations that are issued, but not yet effective, up to the date of issuance of the Company's financial statements are disclosed below. The Company intends to adopt these standards, if applicable, when they become effective.

Amendments to IAS 16 and IAS 38 regarding acceptable methods of depreciation and amortization:

In May 2014, the IASB issued amendments to IAS 16 and IAS 38 ("the amendments") regarding the use of a depreciation and amortization method based on revenue. According to the amendments, a revenue-based method to calculate the depreciation of an asset is not appropriate because revenue generally reflects factors other than the consumption of the economic benefits embodied in the asset.

As for intangible assets, the revenue-based amortization method can only be applied in certain circumstances such as when it can be demonstrated that revenue and the consumption of economic benefits of the intangible asset are highly correlated.

The amendments are to be applied prospectively for annual periods beginning on or after January 1, 2016.

NOTE 5:- OTHER RECEIVABLES AND PREPAID EXPENSES

	December 31,	
	2014	2013
Prepaid expenses	79	9
Due from government authorities	17	6
	96	15

ASPIREO PHARMACEUTICALS LTD.
NOTES TO FINANCIAL STATEMENTS (Continued)
Euro in thousands (except share and per share data)

NOTE 6:- PROPERTY AND EQUIPMENT, NET

	December 31,	
	2014	2013
Cost:		
Computers and software	9	9
Accumulated depreciation	7	6
Depreciated cost	2	3

Depreciation expenses amounted to Euro 1 and Euro 2 for the years ended December 31, 2014 and 2013, respectively.

NOTE 7:- OTHER PAYABLES AND ACCRUED EXPENSES

	December 31,	
	2014	2013
OCS liability	2,078	—
Accrued expenses	219	56
	2,297	56

NOTE 8:- COMMITMENTS AND CONTINGENT LIABILITIES

Until 2003, the Company received and accrued participation payments from the OCS in the aggregate amount of Euro 2,059 in connection with its Somatoprim research and development program. In return for OCS' participation, the Company is committed to pay royalties at a rate of 3% to OCS on sales of the developed product, up to 100% of the amount of grants received plus accrued interest charged to the participation payments at LIBOR. The Company is also committed to repay the grants plus accrued interest in the event of a sale of the intellectual property developed. As of December 31, 2014 the total liability of the Company for the Somatoprim program amounts to Euro 2,426, including accrued interest. Based on advancement of the research and development activities in 2014, the Company's management estimates that it is more likely than not that the Somatoprim program and associated intellectual property will eventually be commercialized. Consequently a liability in the amount of Euro 2,078 was recorded in 2014 and is presented under "Other payables and accrued expenses" in the Statements of Financial Position and as "Other expenses" in the Statements of Profit or Loss.

NOTE 9:- INCOME TAXES

a. Corporate tax rates:

The Israeli corporate tax rate is 25% in 2013 and 26.5% in 2014.

b. Carry forward losses for tax purposes:

The Company has accumulated losses for tax purposes as of December 31, 2014, in the amount of approximately Euro 66,461 which may be carried forward and offset against taxable income in the future for an indefinite period. In addition, the Company has accumulated carry forward capital losses of Euro 7,330.

ASPIREO PHARMACEUTICALS LTD.

NOTES TO FINANCIAL STATEMENTS (Continued)

Euro in thousands (except share and per share data)

- c. Management currently believes that since the Company has a history of losses, and uncertainty exists with respect to future taxable income, it is probable that the deferred tax assets will not be utilized in the foreseeable future. Thus, deferred tax assets were not recorded. In 2014 and 2013, the main reconciling item of the statutory tax rate of the Company (26.5% in 2014 and 25% in 2013) to the effective tax rate (0%) is derived from tax loss carryforwards.
- d. Tax assessment: The Company has received final tax assessments through 2010.

NOTE 10:- SHAREHOLDERS' EQUITY

- a. Ordinary share capital is composed as follows:

	December 31, 2014		December 31, 2013	
	Authorized	Issued and outstanding	Authorized	Issued and outstanding
	Number of shares			
Ordinary shares of NIS 0.10 par value	450,000,000	345,443,386	350,000,000	328,619,838

- b. Ordinary shares rights:

The ordinary shares confer upon their holders the right to participate in the general meetings of the Company, to vote at such meetings (each share represents one vote) and to participate in any distribution of dividends or any other distribution of the Company's property, including the distribution of surplus assets upon liquidation.

- c. Stock Based Compensation

In 2011, the Company's Board of Directors resolved that future issuances of share capital will be shares at par value of NIS 0.10. In addition, issuance of shares to the Company's chief executive officer (CEO) and chief financial officer (CFO), required to maintain their holdings in the Company under their existing agreements (of 5% and 0.5%, respectively), will be at a price equal to 1/1000 of par value.

During the years ended 31, 2014, and 2013 the Company issued shares to its CEO and CFO in order to maintain their ownership percentage of 5% and 0.5% respectively. The table below detailed the number of shares issued to the CEO and CFO during 2014 and 2013, all of which are fully vested:

	2014	2013
CEO	841,178	1,682,354
CFO	84,118	168,236
	925,296	1,850,590

ASPIREO PHARMACEUTICALS LTD.
NOTES TO FINANCIAL STATEMENTS (Continued)
Euro in thousands (except share and per share data)

The total equity-based compensation expense recognized for the years ended December 31, 2014 and 2013 are comprised as follows:

	Year Ended December 31,	
	2014	2013
General and administrative	65	111
Total share-based compensation expense	65	111

NOTE 11:- RELATED PARTY TRANSACTIONS

Compensation of key management:

	Year Ended December 31,	
	2014	2013
Short term benefits ⁽¹⁾	511	542
Share-based compensation expense ⁽²⁾⁽³⁾	65	111
Total	576	653

- (1) Short term benefits comprise fees and benefits earned during the year.
(2) Share-based compensation expense comprises the cost of equity-settled transactions for the period as measured by the fair value of shares issued in accordance with IFRS and as described in Note 10.
(3) In addition, in 2014 and 2013 the Company issued to its parent company 15,898,252 and 31,796,502 shares at par value for total consideration of Euro 1,000 and Euro 1,999 respectively.

NOTE 12:- FINANCE EXPENSES, NET

	Year Ended December 31,	
	2014	2013
Bank charges	3	5
Foreign currency transaction losses, net	7	7
Total financial expenses, net	10	12

NOTE 13:- SUBSEQUENT EVENTS

- a. On June 30, 2015 all closing conditions of the APA with Cortendo were met and accordingly the Company received 22,689,456 shares in Cortendo which were evaluated at Euro 29,530 as of June 30, 2015 based on unadjusted publically quoted price. In addition, Cortendo assumed the OCS liability (see Note 8) and certain other liabilities. As a result, the Company recorded as of June 30, 2015 a gain in the amount of Euro 32,002. Management believes that such gain can be offset against accumulated losses, such that, no tax payment is expected.
- b. On June 8, 2015 the Company received Euro 600 from the parent company on account of an investment in the Company. Upon to the finalization of a share purchase agreement with the parent company, the Company issued an aggregate amount of 9,538,951 ordinary shares to the parent company.

ASPIREO PHARMACEUTICALS LTD.
INTERIM CONDENSED STATEMENT OF FINANCIAL POSITION
Euro in thousands

	June 30, 2015	December 31, 2014
	Unaudited	Audited
	EURO	
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	716	752
Available for sale—financial assets	29,530	—
Other receivables and prepaid expenses	234	96
Total current assets	30,480	848
NON—CURRENT ASSETS:		
Property and equipment, net	3	2
Total non—current assets	3	2
TOTAL ASSETS	30,483	850
LIABILITIES AND SHAREHOLDERS' EQUITY (DEFICIENCY)		
CURRENT LIABILITIES:		
Trade payables	102	76
Other payables and accrued expenses	395	2,297
Total current liabilities	497	2,373
COMMITMENTS AND CONTINGENCIES		
EQUITY ATTRIBUTABLE TO SHAREHOLDERS OF THE COMPANY:		
Share capital	7,405	7,041
Share premium	68,303	67,655
Retained earnings (deficit)	(45,722)	(76,219)
Total equity (deficiency)	29,986	(1,523)
Total liabilities and shareholders' equity (deficiency)	30,483	850

The accompanying notes are an integral part of the financial statements.

ASPIREO PHARMACEUTICALS LTD.
Interim Condensed Statement of Profit or Loss
Euro in thousands

	For the six months ended June 30,	
	2015	2014
	Unaudited EURO	
Operating expenses:		
Research and development	(235)	(340)
General and administrative	(710)	(445)
Other expenses	—	(1,699)
Gain on the sale of the Somatoprim program, net	32,002	—
Total operating income (expenses)	31,057	(2,484)
Operating income (loss)	31,057	(2,484)
Finance expenses, net	(560)	(6)
Net income (loss)	30,497	(2,490)

The accompanying notes are an integral part of the financial statements.

ASPIREO PHARMACEUTICALS LTD.
Interim Condensed Statement of Changes in Equity
Euro in thousands (except share data)

	<u>Number of Ordinary Shares</u>	<u>Amount</u>	<u>Share premium</u>	<u>Retained deficit</u>	<u>Equity (Deficiency) attributable to shareholders of the Company</u>
Balance as of January 1, 2015	345,443,386	7,041	67,655	(76,219)	(1,523)
Issuance of ordinary shares to parent					
Company	9,538,951	228	372	—	600
Share based payment transactions	5,888,239	136	276	—	412
Net income	—	—	—	30,497	30,497
Balances as of June 30, 2015 (Unaudited) .	<u>360,870,576</u>	<u>7,405</u>	<u>68,303</u>	<u>(45,722)</u>	<u>29,986</u>
Balance as of January 1, 2014	328,619,838	6,682	66,949	(72,431)	1,200
Net loss	—	—	—	(2,490)	(2,490)
Balances as of June 30, 2014 (Unaudited) .	<u>328,619,838</u>	<u>6,682</u>	<u>66,949</u>	<u>(74,921)</u>	<u>(1,290)</u>

The accompanying notes are an integral part of the financial statements.

ASPIREO PHARMACEUTICALS LTD.
Interim Condensed Statement of Cash Flows
Euro in thousands

	Six months ended	
	June 30,	
	2015	2014
	Unaudited	
	EURO	
Cash flows from operating activities:		
Net income (loss)	30,497	(2,490)
Adjustments to reconcile net loss to net cash used in operating activities:		
Adjustments to the profit or loss items:		
Gain from the sale of the Somatoprim program, net	(32,002)	—
Share-based payment transactions	412	—
Changes in assets and liabilities:		
Increase in receivables and prepaid expenses	(138)	—
Increase (decrease) in trade payables	26	(75)
Increase (decrease) in other payables and accrued expenses	(1,902)	1,746
Net cash used in operating activities	<u>(3,107)</u>	<u>(819)</u>
Cash flows from investing activities:		
Purchase of equipment	(1)	—
Proceeds from the sale of the Somatoprim program	2,472	—
Net cash provided by investing activities	<u>2,471</u>	<u>—</u>
Cash flows from financing activities:		
Issuance of share capital to parent company	600	—
Net cash provided by financing activities	<u>600</u>	<u>—</u>
Decrease in cash and cash equivalents	(36)	(819)
Cash and cash equivalents at the beginning of the year	752	1,329
Cash and cash equivalents at the end of the period	<u>716</u>	<u>510</u>
Supplemental information and disclosure of non-cash investing transactions:		
Financial assets available for sale (see also Note 10)	29,530	—

The accompanying notes are an integral part of the financial statements.

ASPIREO PHARMACEUTICALS LTD.
NOTES TO THE INTERIM CONDENSED FINANCIAL STATEMENTS
Euro in thousands (except share and per share data)

NOTE 1:- CORPORATE INFORMATION:

- a. Aspireo Pharmaceuticals Limited (the “Company”) was established in 1992 and started activities in 1993. The Company was previously engaged in research and development of treatments for diabetes, autoimmune diseases and other research programs and since 2010, the Company is focused solely on the development of somatostatin analogs for the potential treatment of acromegaly, Cushing’s disease, carcinoid tumors and diabetic retinopathy.

TVM V Life Science Ventures GmbH & Co KG. is the parent company.

The Company sole development compound is Somatoprim (DG3173), a proprietary somatostatin analog that is based on a novel amino acid composition and a unique backbone cyclization technology used for stabilization of the peptide.

The Company’s activities since inception have consisted principally of raising capital and performing research and development activities. Since the sale of Somatoprim to Cortendo (see note 1c.), the Company has taken the required steps to transfer the Somatoprim project to Cortendo. There are currently no plans to engage in further research and development activities.

- b. As of June 30, 2015, the Company had cash and cash equivalents of Euro 716. In addition, as of the same date, the Company had financial assets available for sale in the amount of Euro 29,530. In accordance with the agreement with Cortendo (see Note 1c.) such financial assets are subject to certain lock-up agreements. During the six months period ended June 30, 2015 the Company generated net income of Euro 30,497 which was mainly attributable to the sale of Somatoprim program (see also Note 1c and Note 10) and had negative cash flows from operating activities of Euro 3,107. In addition, the Company had a retained deficit of Euro 45,722 at June 30, 2015. The Company estimates that it has sufficient cash and cash equivalents through June 30, 2016.

- c. On May 14, 2015, the Company entered into an Asset Purchase Agreement (“APA”) with Cortendo AB (“Cortendo”), a Swedish company listed in Norway—NOTC, regarding the purchase by Cortendo of Aspireo’s Somatoprim (DG3173) program. Under the terms of the agreement, Cortendo acquired all rights and obligations in the Somatoprim program and assumed responsibility for the further development and commercialization of the Somatoprim program. As consideration for the sale, Aspireo received \$30 million worth of shares in Cortendo, amounting 22,689,456 shares. The number of shares was determined based on the fair value of Cortendo shares on the date of signing the APA. In addition, Cortendo also assumed the OCS liability (see Note 6).

Management believes that as of June 30, 2015, all closing conditions of the APA were met. The fair value of the shares on the close date was approximately \$33 million.

Following the close of the APA on June 30, 2015 the Company has no principal operational activity except for the holding of the Cortendo shares received as consideration for the sale of the Somatoprim program.

The disposal of substantially all the operations of the Company does not qualify as a discontinued operation under IFRS 5.

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NOTES TO THE INTERIM CONDENSED FINANCIAL STATEMENTS (Continued)
Euro in thousands (except share and per share data)

- d. The financial statements of the Company have been prepared in accordance with International Financial Reporting Standards (IFRS) as issued by the International Accounting Standards Board (IASB).
- e. Basis of presentation of the financial statements:
The Company's financial statements have been prepared on a historical cost basis. The Company has elected to present profit or loss items using the function of expenses method.

NOTE 2:- BASIS OF PREPARATION AND CHANGES TO THE COMPANY'S ACCOUNTING POLICIES

- a. Basis of preparation
The interim condensed financial statements for the six months ended June 30, 2015 have been prepared in accordance with IAS 34 Interim Financial Reporting.
The interim condensed financial statements do not include all the information and disclosures required in the annual financial statements, and should be read in conjunction with the Company's annual financial statements as of December 31, 2014.
- b. Available for Sale—Financial assets
Financial assets are classified, at initial recognition, as financial assets at fair value.
After initial measurement, available for sale financial assets (AFS) are subsequently measured at fair value with unrealized gains or losses recognized in other comprehensive income and credited in the AFS reserve until the investment is derecognized, at which time the cumulative gain or loss is recognized in other operating income. In the event the investment is determined to be impaired, the cumulative loss is reclassified from the AFS reserve to the statement of profit or loss.
- c. Fair value
All assets and liabilities for which fair value is measured or disclosed in the financial statements are categorized within the fair value hierarchy, described as follows, based on the lowest level input that is significant to the fair value measurement as a whole:
 - 1) Level 1—Quoted (unadjusted) market prices in active markets for identical assets or liabilities
 - 2) Level 2—Valuation techniques for which the lowest level input that is significant to the fair value measurement is directly or indirectly observable
 - 3) Level 3—Valuation techniques for which the lowest level input that is significant to the fair value measurement is unobservableFor the purpose of fair value disclosures, the Company has determined classes of assets and liabilities on the basis of the nature, characteristics and risks of the asset or liability and the level of the fair value hierarchy as explained above. The fair value of financial instruments that are traded in an active market is determined by reference to market prices at the end of the reporting period. For financial instruments where there is no active market, fair value is determined using valuation techniques. Such techniques include using recent arm's length market transactions, reference to the

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current market value of another instrument which is substantially the same, discounted cash flow and other valuation models.

The available for sale financial assets received from the sale of the Somatoprim program are classified as level 1 in the fair value hierarchy, see also Note 10 below.

d. New standards, interpretations and amendments adopted by the Company

The accounting policies adopted in the preparation of the interim condensed financial statements are consistent with those followed in the preparation of the Company's annual financial statements for the year ended December 31, 2014, except for the adoption of new standards and interpretations effective as of January 1, 2015. The Company has not early adopted any other standard, interpretation or amendment that has been issued but is not yet effective. The nature and the effect of these changes are disclosed below. Although these new standards and amendments apply for the first time in 2015, they do not have a material impact on the annual financial statements of the Company or the interim condensed financial statements of the Company.

IFRS 2 Share-based Payment:

This improvement is applied prospectively and clarifies various issues relating to the definitions of performance and service conditions which are vesting conditions, including:

- A performance condition must contain a service condition.
- A performance target must be met while the counterparty is rendering service.
- A performance target may relate to the operations or activities of an entity, or to those of another entity in the same group.
- A performance condition may be a market or non-market condition.
- If the counterparty, regardless of the reason, ceases to provide service during the vesting period, the service condition is not satisfied.

The above definitions are consistent with how the Company has identified any performance and service conditions which are vesting conditions in previous periods, and thus these amendments do not impact the Company's accounting policies.

IAS 24 Related Party Disclosures:

The amendment is applied retrospectively and clarifies that a management entity (an entity that provides key management personnel services) is a related party subject to the related party disclosures. In addition, an entity that uses a management entity is required to disclose the expenses incurred for management services. This amendment is not relevant for the Company as it does not receive any management services from other entities.

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NOTES TO THE INTERIM CONDENSED FINANCIAL STATEMENTS (Continued)
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NOTE 3:- OTHER RECEIVABLES AND PREPAID EXPENSES

	June 30,	December 31,
	2015	2014
	Unaudited	Audited
Due from Cortendo ⁽¹⁾	187	—
Prepaid expenses	16	79
Due from government authorities	31	17
	234	96

(1) Under the terms of the APA, Cortendo acquired all of the existing research and development contracts with regard to the Somatoprim program. Additionally, Cortendo assumed the costs associated with on-going research and development activities between the date of the APA and the close date. The costs assumed by Cortendo were approximately Euro 168 and as such no expense was recorded in the statement of profit or loss in regards as such research and development activities in the stated period.

NOTE 4:- PROPERTY AND EQUIPMENT, NET

	June 30,	December 31,
	2015	2014
	Unaudited	Audited
Cost:		
Computers and software	10	9
Accumulated depreciation	7	7
Depreciated cost	3	2

Depreciation expenses amounted to less than Euro 1 for both six months periods ended June 30, 2015 and 2014.

NOTE 5:- OTHER PAYABLES AND ACCRUED EXPENSES

	June 30,	December 31,
	2015	2014
	Unaudited	Audited
OCS liability	—	2,078
Accrued expenses	395	219
	395	2,297

NOTE 6:- COMMITMENTS AND CONTINGENT LIABILITIES

Until 2003, the Company received and accrued participation payments from the Office of the Chief Scientist of the Ministry of Economy in Israel (“OCS”) in the aggregate amount of Euro 2,059 in connection with its Somatoprim research and development program. In return for OCS’ participation, the Company is committed to pay royalties at a rate of 3% to OCS on sales of the developed product, up to 100% of the amount of grants received plus accrued interest charged to the participation

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payments at LIBOR. The Company is also committed to repay the grants plus accrued interest in the event of a sale of the intellectual property developed. Based on advancement of the research and development activities in 2014, the Company's management estimated that it is more likely than not that the Somatoprim program and associated intellectual property will eventually be commercialized. Consequently a liability in the amount of Euro 1,699 was recorded in the in the six months ended June 30, 2014 and is presented under "Other payables and accrued expenses" in the Statements of Financial Position and as "Other expenses" in the Statements of Profit or Loss.

As of June 30, 2015, consequently to the sale of Somatoprim program (see also Note 10), the Company repaid in full its outstanding liability to OCS in the amount of Euro 2,655, including accrued interest.

NOTE 7:- INCOME TAXES

a. Corporate tax rates:

The Israeli corporate tax rate is 26.5% in 2015 and in 2014.

b. Carry forward losses for tax purposes:

The Company has accumulated losses for tax purposes as of December 31, 2014, in the amount of approximately Euro 66,461 which may be carried forward and offset against taxable income in the future for an indefinite period. In addition, the Company has accumulated carry forward capital losses of Euro 7,330.

See Note 10 for information on the gain on the sale of the Somatoprim program.

Management believes that such net gain on the sale of the Somatoprim program can be offset against the accumulated losses above.

c. Management currently believes that since the Company has a history of losses, and uncertainty exists with respect to future taxable income, it is probable that the deferred tax assets will not be utilized in the foreseeable future. Thus, deferred tax assets were not recorded. In the six months ended June 30, 2015 and 2014, the main reconciling item of the statutory tax rate of the Company (26.5%) to the effective tax rate (0%) is derived from tax loss carryforwards.

d. Tax assessment: The Company has received final tax assessments through 2010.

NOTE 8:- SHAREHOLDERS' EQUITY

a. Ordinary share capital is composed as follows:

	<u>June 30, 2015</u>		<u>December 31, 2014</u>	
	<u>Unaudited</u>		<u>Audited</u>	
	<u>Authorized</u>	<u>Issued and outstanding</u>	<u>Authorized</u>	<u>Issued and outstanding</u>
	<u>Number of shares</u>			
Ordinary shares of NIS 0.10 par value	<u>450,000,000</u>	<u>360,870,576</u>	<u>450,000,000</u>	<u>345,443,386</u>

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b. Ordinary shares rights:

The ordinary shares confer upon their holders the right to participate in the general meetings of the Company, to vote at such meetings (each share represents one vote) and to participate in any distribution of dividends or any other distribution of the Company's property, including the distribution of surplus assets upon liquidation.

c. On June 8, 2015 the Company received Euro 600 from the parent company on account of an investment in the Company and issued an aggregate amount of 9,538,951 ordinary shares to the parent company.

d. Stock Based Compensation

In 2011, the Company's Board of Directors resolved that future issuances of share capital will be shares at par value of NIS 0.10. In addition, it was further resolved that future issuance of shares to the Company's chief executive officer (CEO) and chief financial officer (CFO) would be at a price equal to 1/1000 of par value. In June 2015, the Board of Directors resolved to issue shares to the chief business officer (CBO) and to an advisor under the same terms and conditions.

The table below detailed the number of shares issued to CEO, CFO, CBO and advisor during the six months ended June 30, 2015, all of which are fully vested:

	Six months ended June 30, 2015
	Unaudited
CEO	504,706
CFO	939,314
CBO	2,666,531
Advisor	1,777,688
	5,888,239

The total equity-based compensation expense recognized for the six months ended June 30, 2015 are comprised as follows:

	Six months ended June 30, 2015
	Unaudited
General and administrative	288
Compensation expense related to the sale of the Somatoprim program	124
Total share-based compensation expense	412

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NOTES TO THE INTERIM CONDENSED FINANCIAL STATEMENTS (Continued)
Euro in thousands (except share and per share data)

NOTE 9:- RELATED PARTY TRANSACTIONS

Compensation of key management:

	Six months ended June 30,	
	2015	2014
	Unaudited	Unaudited
Short-term benefits	253	259
Share-based compensation expense	288	—
Total	541	259

1. Short term benefits comprise fees and benefits earned during the year.
2. Share-based compensation expense comprises the cost of equity-settled transactions for the period as measured by the fair value of shares issued in accordance with IFRS and as described in Note 8.
3. In addition, in the six months ended June 30, 2015 the Company issued to its parent company 9,538,951 shares at par value for total consideration of Euro 600.

NOTE 10:- GAIN ON THE SALE OF THE SOMATOPRIM PROGRAM

On June 30, 2015 all closing conditions of the APA with Cortendo were met and accordingly the Company received 22,689,456 shares in Cortendo which were evaluated at Euro 29,530 as of June 30, 2015 based on unadjusted publically quoted price. In addition, Cortendo assumed the OCS liability (see Note 6) and certain other liabilities. As a result, the Company recorded as of June 30, 2015 a gain in the amount of Euro 32,002. Management believes that such gain can be offset against accumulated losses, such that, no tax payment is expected (see also Note 7).

Until November 10, 2015, 25 days after the date of this prospectus, all dealers that effect transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.



2,500,000 Ordinary Shares

PROSPECTUS

Stifel

JMP Securities

Roth Capital Partners

Arctic Securities

October 16, 2015
